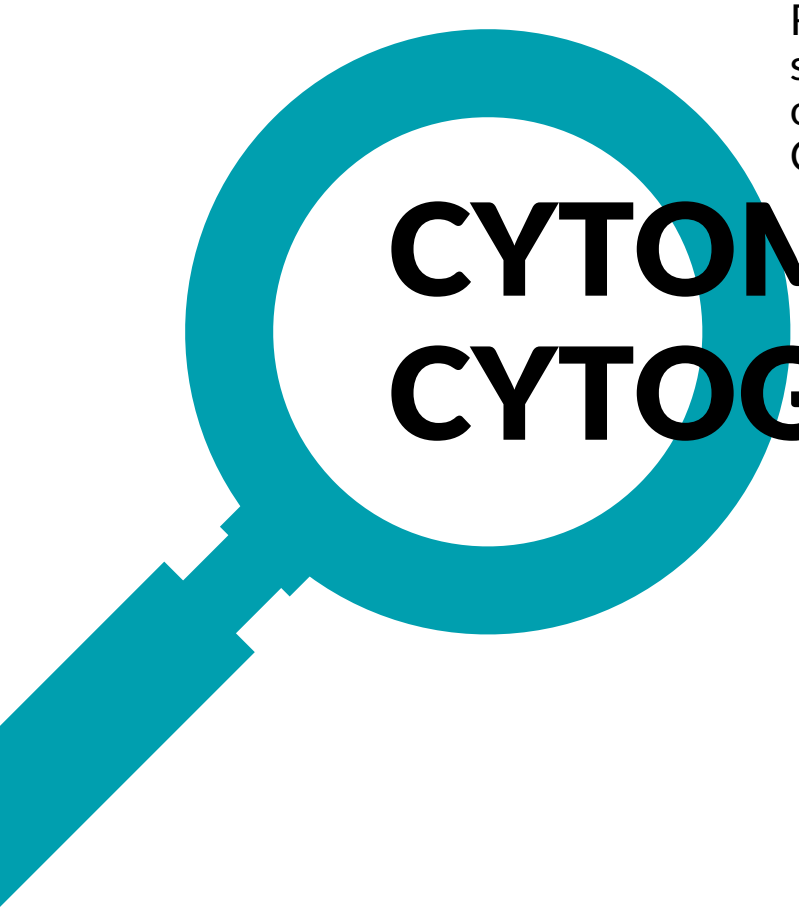
PEPTIDES

Санкт-Петербургский
Институт биорегуляции
и геронтологии

Reports on the results of clinical studies of peptide bioregulators of the CYTOMAX AND CYTOGEN class.

CYTOMAXES AND CYTOGENES



www.peptidesco.com

Reports on the results of clinical studies of peptide bioregulators of the CYTOMAX AND CYTOGEN class.

Introduction

The aging of the body is one of the most mysterious and relevant topics in modern medicine. For centuries, scientists worldwide have been trying to answer these questions: how to prolong youth? How to maintain good health? How to stay active for a long time? In Russia, this issue has been resolved by the St. Petersburg Institute of Bioregulation and Gerontology under the guidance of Professor V. Khavinson. As a result of numerous clinical studies, physiologically active proteins have been discovered - peptides, which help the body naturally restore itself.

In the new edition, we combined all the scientifically proven results of the use of peptide bioregulators of the Cytomax class (21 geroprotectors) and Cytogenes (6 geroprotectors). These studies confirm that peptides of natural origin («Cytomaxes») harmonize metabolic processes in human cells. In the long term, this reduces the risk of cancer, slows down premature aging, and increases life expectancy. In turn, «Cytogenes», synthesized from natural amino acids, have a faster effect at the initial stage, starting up the function of restoring internal organs. Physiologically active short peptides should be used at any age to maintain a normal level of metabolic processes, prevent and treat various diseases, for rehabilitation after serious illnesses, injuries, or surgeries, and for slowing down the body's aging process. Both classes of Peptides bioregulators have no side effects, as they contain peptides, which are part of the human body.

For your convenience, we have added a section - recommendations for use.

With care,
Team Peptides

21 geroprotectors

CYTOMAXES

The effectiveness of peptide bioregulators has been proven by many years of clinical studies. Bioregulators based on natural peptides help slow down premature aging and normalize metabolic processes in the body's cells, starting their natural renewal process and increasing life expectancy. Cytomaxes are safe to use and have no side effects or withdrawal syndrome.

St. Petersburg

Bonomarlot®

Report on the results of clinical studies of the biologically active food supplement **BONOMARLOT®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement BONOMARLOT® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, extracted from bone marrow tissue of young animals - calves not older than 12 months of age or pigs.
BONOMARLOT® is available in capsules with an active substance content of 10 mg.
BONOMARLOT® peptides regulate metabolic processes in the cells of the hematopoietic system, increase its reserve capabilities, have a beneficial effect on the adaptation processes of the body in extreme conditions, and have antioxidant properties regulating the processes of peroxidation in the cells of the hematopoietic system. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This allows us to assume the effectiveness of the use of BONOMARLOT® for restoring the functions of the hematopoietic system in the case of its disorders of various origins, primarily in anemia.
Anemia is not an independent disease, but it occurs as a syndrome in a number of diseases that can either be associated with a primary injury of the blood system or not depend on it. Therefore, anemia is a widespread condition that requires targeted treatment, as the quality of life of people with anemia is drastically reduced.
Any anemia leads to a decrease in the respiratory function of the blood and the development of oxygen starvation of tissues, which is most often expressed by such symptoms as pallor of the skin, increased fatigue, weakness, headaches, dizziness, rapid heartbeat, shortness of breath and others. A decrease in hemoglobin concentration in the blood often occurs with a simultaneous reduction in the number of red blood cells and their qualitative composition changes. In this case, it is essential to preserve the ability of the bone marrow to regenerate, which is manifested by an increase in the number of reticulocytes (young erythrocytes) in the peripheral blood (the norm is 0.5% -2%). Maintaining the regenerative activity of the bone marrow helps to level the symptoms of anemia and improve the patient's general condition.
In general, the treatment tactics depend on the type of anemia and the severity of the patient's condition. Currently, vitamin B12 and iron supplements are mainly used to treat anemia. Also, with a low hemoglobin level, red blood cell transfusions can be performed.

CLINICAL CHARACTERISTICS OF PATIENTS
A clinical study of the efficacy of BONOMARLOT® took place at the Medical Center of the Saint Petersburg Institute of Bioregulation and Gerontology of the Northwest Branch of the Russian Academy of Medical Sciences from April to November 2011.
The clinical study involved 26 women aged 35 to 56 years with signs of mild to moderate iron-deficiency anemia due to malnutrition.
Patients complained of weakness, rapid fatigue, general malaise, decreased concentration, shortness of breath after light or moderate physical activity, palpitations, headache, tinnitus, sleep, and appetite disturbances.
An objective examination revealed pallor of the skin of visible mucous membranes and nail beds, as well as the appearance of functional systolic murmurs in most patients.
During laboratory examinations, the patients showed a decrease in the hemoglobin content in the blood to a level of 70-90 g/l, which indicates the presence of mild or moderate anemia.
All patients were divided into 2 groups. Patients in the control group (11 people) received conventional therapy, including iron supplements, vitamin B12, and a special diet. In addition to conventional treatment, patients of the primary group (15 people) received BONOMARLOT® 1 capsule 2 times a day with meals for 30 days.

RESEARCH METHODS
We assessed the patients' complaints and conducted general clinical blood tests during the study.

RESEARCH RESULTS
The use of BONOMARLOT® in patients with mild and moderate anemia improved the general condition,

which was manifested in a decrease in weakness, rapid fatigue, general malaise, and shortness of breath after light or moderate physical activity. The drug's effect also decreased palpitations, headaches, tinnitus, sleep disturbances, appetite, and increased concentration and performance (Table 1). It is important to note that the improvement in the condition of patients of the primary group occurred in a shorter time than in the control group, which used only conventional therapy. If in the patients of the control group, the improvement in the condition occurred on average after 35.6 ± 2.7 days, then in the patients of the primary group - after 26.2 ± 1.6 days. Thus, the time of improvement in patients with anemia with the use of BONOMARLOT®, in addition to conventional therapy, was reduced by 24.4%.

Dynamics of subjective indicators in patients with anemia

Table 1

Indicator	Number of patients, %		
	Before treatment	After treatment with conventional therapy (control group)	After treatment with BONOMARLOT® (primary group)
Weakness	96,0	58,2*	25,4*#
Shortness of breath	78,2	48,5*	21,3*#
Rapid fatigability	82,2	63,2*	29,5*#
Reduced performance	92,4	67,3*	34,7*#
Tinnitus	74,1	42,1*	23,1*#
Decreased concentration of attention	89,5	57,5*	34,1*#
Headaches	68,4	41,8*	26,4*#
Palpitations	65,9	38,3*	21,7*#
Sleep disturbances	77,6	47,3*	29,1*#

* p <0.05 reliable in comparison with the indicator in patients before treatment;
# p <0.05 reliable in comparison with the indicator in patients after treatment with conventional means.

Effect of BONOMARLOT® on the content of erythrocytes and hemoglobin in the blood serum of patients with anemia

Table 2

Indicator	Norm	Before treatment	After treatment with conventional therapy (control group)	After treatment with BONOMARLOT® (primary group)
Erythrocytes, (×10 12/l)	3,7-4,7	3,3±0,7	3,6±0,4	3,7±0,5
Hemoglobin, (g/l)	115-145	77,8±2,8	95,4±3,2*	112,6±4,2*#

* p <0.05 –reliable in comparison with the indicator in patients of the control group.
# p <0.05 –reliable in comparison with the indicator in patients of the control group.

In the laboratory study, after the use of BONOMARLOT®, a significant improvement in the parameters of the content of erythrocytes and hemoglobin in the blood was noted. As expected, it was more pronounced than the indicators in the patients of the control group (Table 2).
The noted changes in the parameters in the peripheral blood of patients while taking BONOMARLOT® correlate with clinical indicators. They indicate the restoration of an adequate response of the body's hematopoietic system in response to malnutrition.
Analysis of the data allows us to conclude that BONOMARLOT® has a normalizing effect on cellular

metabolism in the tissues of the bone marrow, helps restore the functions of the hematopoietic system in women with alimentary anemia.
Thus, the results obtained indicate the therapeutic efficacy of BONOMARLOT® and the practicality of its use in the complex treatment of patients of different ages with anemia of various origins.
When using BONOMARLOT®, no side effects, complications, or drug dependence have been identified.
BONOMARLOT® can be used for therapeutic and prophylactic purposes in the form of a biologically active food supplement combined with any means of symptomatic and pathogenetic therapy used to treat anemia of various origins.

CONCLUSION

Biologically active food supplement BONOMARLOT® has a normalizing effect on the functional activity of bone marrow cells.
BONOMARLOT® is well tolerated when taken orally, has no side effects, and can be used for therapeutic and prophylactic purposes as a biologically active food supplement.
BONOMARLOT® is recommended for use to patients with anemia of various origins orally during meals, 1-2 capsules 2 times a day for 30 days.
It is recommended to repeat the course of treatment after 3-6 months.

REFERENCES

1. Belousov Y.B., Moiseev V.S., Lepakhin V.K. Clinical Pharmacology and Pharmacotherapy: A Guide for Physicians. - M .: the Universe, 1993 .-- 398 p.
2. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
3. Geriatric manual / Ed. D.F. Chebotarev, N.B. Mankovsky. – M.: Medicine, 1982. – 544 p.
4. Pogorelov V.M., Kozinets G.I., Kovaleva L.G. Laboratory and clinical diagnostics of anemia. - M., 2004 .-- 172 p.
5. Shiffman F.D. Clinical approach to patients with hematological profile. - In the book: Blood pathophysiology. - SPb., 2001 .-- S. 43-71.

RECOMMENDATIONS FOR USE

BONOMARLOT® is a complex of peptides obtained from the bone marrow of young animals. The extracted peptides have a selective effect on bone marrow cells, normalize metabolism in bone marrow cells, and regulate the functions of the hematopoietic system.
Clinical studies established the effectiveness of BONOMARLOT® in the complex treatment of patients with anemia of various origins when exposed to extreme environmental factors, malnutrition, and the use of diets to reduce weight.
Bonomarlot® instructions: 1-2 capsules or tablets 1-2 times a day with meals. The duration of administration is 30 days. It is advisable to repeat the course in 3-6 months.
Do not use if: you suffer from individual intolerance to the components, pregnancy, breastfeeding.
There were no side effects noticed when using BONOMARLOT®.
Store in a dry, dark place at a temperature from +2 to +25 °C.
Release form: 20 capsules or tablets containing 10 mg of BONOMARLOT®.
Expiration date: 3 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Bonothyrk®

Report on the results of clinical studies of the biologically active food supplement **Bonothyrk®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement BONOTHYRK® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the tissues of the parathyroid glands of young animals - calves under 12 months of age or pigs.
BONOTHYRK® is available in capsules with an active substance content of 10 mg.
Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. BONOTHYRK® peptides regulate metabolic processes in the cells of the parathyroid glands, increase their reserve capabilities while causing a beneficial effect on the adaptation processes of the body in extreme conditions. They also possess antioxidant properties and regulate the peroxidation processes in the tissues of the parathyroid glands. This allows us to assume the effectiveness of BONOTHYRK® to restore the functions of bone tissue in case of injuries of various origins, especially in women over 50 years old.
Bones become thinner, less solid, and elastic with age. This is partly because after you turn 35, calcium escapes the bones more than it retains in bone tissue. This is common for everyone, but it is especially pronounced in some people and leads to osteoporosis. Among all the factors that ensure the strength of the skeleton, the ratio of calcium to magnesium is vital. When magnesium in the blood drops, the kidneys regain balance, keeping less calcium in. When the concentration of magnesium increases, the kidneys release less calcium. For this reason, the body primarily needs magnesium and vitamin B6, which contributes to the retention of magnesium in the cells.
Osteoporosis affects the entire skeleton, especially hip- bones, bones of the forearm, and vertebrae. Even a weak impact (for example, a fall in the street) can lead to a fracture. Moreover, in the case of vertebrae, compression fractures can occur even in the absence of external influence - as a result of the pressure created by the body's own weight. This kind of damage, as well as the flattening of the cartilaginous intervertebral discs due to their loss of elasticity, is the reason that in old age, a person starts to shrink, and his posture deteriorates.
Osteoporosis is widespread in older women: after the age of 60, one in four suffers from it. In men, it occurs four times less often. The fact is that before menopause (age-related cessation of menstruation), the strength of the bones is maintained by estrogens, and after it, their level in the body decreases. Estrogens are antagonists (agents with the opposite effect) of the parathyroid hormone, which stimulates an increase in calcium concentration in the blood. This is due to the «washing out» of calcium from the bones. Therefore, the deficiency of female sex hormones leads to a decrease in their strength, that is, the likelihood of a fracture in elderly women increases.
To prevent osteoporosis, estrogens are prescribed, either to be taken orally or in the form of subcutaneous implants. A balanced diet rich in natural vitamins, minerals (especially calcium), and fiber, as well as regular exercise, also help maintain bone strength. The most effective prevention of osteoporosis is the inclusion of whole grains in the diet (especially bread made from unrefined wholemeal flour). The risk of developing osteoporosis increases with smoking, drinking, and a sedentary lifestyle.
Given the significant number of contraindications and side effects when using hormone therapy, it is important to continue the search for effective means that help prevent the development of osteoporosis but do not cause side effects.

CLINICAL CHARACTERISTICS OF PATIENTS

A clinical study of BONOTHYRK® efficiency as part of the complex prevention of osteoporosis took place at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology in the period from March to December 2011.
The clinical study involved 33 women aged 47 to 56 years with a mild to moderate climacteric syndrome diagnosis, who showed a decrease in bone mineral density of more than 20% of the normal value, which indicated an increased risk of osteoporosis.
The patients were divided into 2 groups. 13 people included in the control group did not take drugs aimed at increasing bone mineral density. 20 patients in the primary group used BONOTHYRK® - 2 capsules 2 times a day for 30 days.

The state of the bone tissue was determined by the method of X-ray densitometry and by observing the dynamics of the decrease in bone mineral density - before the start of treatment and 3 months after the end of the course of using BONOTHYRK®.

RESEARCH RESULTS

The use of BONOTHYRK® in patients with an initially reduced indicator of bone mineral density (BMD) contributed to the prevention of the progression of bone tissue demineralization (table).

Dynamics of bone mineral density in patients with climacteric syndrome Table

Decreased BMD	Number of patients,%		
	Initial level	After 3 months. (control group)	After 3 months using BONOTHYRK® (main group)
15-20%	90,5	85,6	94,7
20-25%	9,5	14,4	5,3

* p <0.05 reliablein comparison with the indicator in patients before treatment;
# p <0.05 reliable in comparison with the indicator in patients after treatment with conventional means.

As you can see from the data shown in the table, at the end of the course with BONOTHYRK®, the progression of the decrease in bone mineral density in patients of the primary group slowed down. The number of patients who had a decrease in BMD of no more than 20% increased from 90.5% (initially) to 94.7% after the course of treatment, which indicates an emerging trend of inhibition of the process of bone demineralization. In the control group patients who did not take drugs aimed at inhibiting the process of bone demineralization, the number of patients with a decrease in bone mineral density of more than 20% increased from 9.5% (initially) to 14.4% after 3 months, which creates an unfavorable prognosis in terms of the development of osteoporosis.
Thus, the obtained results of the study indicate the preventive and therapeutic efficacy of BONOTHYRK® and the advisability of its use in the complex treatment of patients of different ages who are at risk of developing osteoporosis.
When using BONOTHYRK®, no side effects, complications, or drug dependence were observed.
BONOTHYRK® can be used for therapeutic and prophylactic purposes in the form of a biologically active food supplement combined with any means of symptomatic and pathogenetic therapy used to treat osteoporosis.

CONCLUSION

Biologically active food supplement BONOTHYRK® has a normalizing effect on the functional activity of bone cells.
BONOTHYRK® is well tolerated when taken orally, has no side effects, and can be used as a therapeutic and prophylactic biologically active food supplement.
BONOTHYRK® is recommended for the complex treatment of patients with early-stage osteoporosis, orally during meals, 1-2 capsules 2 times a day for at least 30 days.
It is recommended to repeat the course of treatment after 3-6 months.

REFERENCES

1. Benevolenskaya L.I. Osteoporosis - an urgent problem of medicine // Osteoporosis and Osteopathy. - 1998. - №1 - 4-7pp.
2. Mikhailov E.E. Benevolenskaya L.N., Anikin S.G. et al. Osteoporosis and Osteopathy. 1999; 3: 2-6
3. RozhinskayaL.Ya. Systemic osteoporosis. M., 2001; with. 46-64
4. Chen XD, Shi S, Xu T, Robey PG, Young MF. Age-related osteoporosis in biglycan-deficient mice is related to defects in bone marrow stromal cells. J Bone Miner Res. 2002Feb;17(2):331-40
5. Clarke H., Anderson H. An Antagonist of Osteoclast Integrins Prevents Experimental Osteoporosis // J. Clin. Invest. Volume 99, Number 9, May 1997, 2059-2059

RECOMMENDATIONS FOR USE

BONOTHYRK® is a complex of peptides obtained from the parathyroid glands of young animals. The extracted peptides have a selective effect on the cells of the parathyroid glands, normalize metabolism in the cells of the parathyroid glands, and regulate the functions of bone tissue, especially in older women.
A clinical study established the effectiveness of BONOTHYRK® in the prevention and complex treatment of patients with osteoporosis, including women over the age of 50.
Bonothyrk® instructions: 1-2 capsules or tablets with meals 1-2 times a day. The duration of administration is 30 days. It is advisable to repeat the course in 3-6 months.
Do not use if: you suffer from individual intolerance to the components, pregnancy, breastfeeding.
There were no side effects observed when using BONOTHYRK®.
Store in a dry, dark place at a temperature from +2 to +25 °C.
Release form: 20 capsules or tablets containing 10 mg of BONOTHYRK®.
Expiration date: 3 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Ventfort®

Report on the results of clinical studies of the biologically active food supplement **Ventfort®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

The biologically active food supplement VENTFORT® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, extracted from the tissue of the vessels (aorta) of young animals - calves up to 12 months of age or pigs.
VENTFORT® is available in tablets or capsules with an active ingredient content of 10 mg.
Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. They improve the tropism of the cells of the tissues of the vascular wall and have a regulatory effect on metabolic processes in them, contribute to the normalization of functional and morphological changes in the vascular wall, regulate the content of cholesterol and lipoproteins in the blood, reducing the risk of various vascular diseases. This suggests the effectiveness of the use of VENTFORT® for the restoration of vascular function in various conditions, including vascular atherosclerosis.
Atherosclerosis and its consequences are one of the leading causes of disability and death in developed countries. Changes in the vascular wall that increase with age and impaired hemodynamics lead to decreased peripheral blood circulation, vascularization of organs and tissues, the development of various components of oxygen deficiency, and trophic disorders (2, 3, 4, 6).
Drug treatment of atherosclerosis aims to normalize lipid metabolism, blood coagulation, and metabolism in the vascular wall (1, 5).

Medicines that normalize cholesterol and β-lipoprotein levels:
- Drugs, which prevent the absorption of cholesterol in the intestine (cholestyramine, β-sitosterol, diosponin, polisponin);
- Drugs, which interrupt the synthesis of cholesterol in the body (clofibrate, miscleron, regardin, cetamifen, nicotinic acid, vitamin PP);
- Drugs, which enhance the splitting and excretion of cholesterol from the body (linetol, arachidene).
- Drugs, which improve microcirculation, normalize vascular permeability, reduce swelling of vascular tissues and improve metabolic processes in the vascular wall (prodectin, dicinone, doxium, glivenol, escuzan, etc.)
Clinical trials of VENTFORT® took place at the Medical Center of the Saint Petersburg Institute of Bioregulation and Gerontology of the Northwest Branch of the Russian Academy of Medical Sciences in patients with atherosclerosis of various arteries and senile purpura in the period from November 2005 to February 2006.

CLINICAL CHARACTERISTICS OF PATIENTS

The clinical trials involved 49 patients with atherosclerosis of the arteries and senile purpura, 27 of whom made up the primary group (15 men, 12 women) - in addition to conventional drugs, they took VENTFORT® orally 10-15 minutes before meals, 1-2 capsules 2-3 times a day for 10-15 days, depending on the severity of the pathological process. Another 22 patients (11 men, 11 women) included in the control group were prescribed only general-purpose drugs. The age of patients in both groups ranged from 52 to 84 years (Table 1).
Patients of both groups had different clinical symptoms depending on the lesions of vessels of varying caliber: hypertension, coronary heart disease, cerebrovascular disorders with impaired memory, concentration, and affective lability. All patients showed progressive dynamics of disease development.
All patients previously received symptomatic and pathogenetic therapy for specific clinical symptoms of vascular pathology.

Division of patients by nosological forms, sex and age

Table 1

Diagnosis	Age (years)	Male		Female		Total	
		Control group	Primary group	Control group	Primary group	Control group	Primary group
Atherosclerosis of the arteries	52-71	9	11	6	9	15	20
Senile purpura	72-84	2	4	4	3	7	7
Total		11	15	10	12	22	27

RESEARCH METHODS

The patients' complaints were assessed in dynamics. A general clinical examination of blood and urine and a biochemical study of blood on the «REFLOTRON» apparatus (Boehringer Mannheim, Germany) were carried out. To study homeostasis, we assessed the blood coagulogram, and the Hess test was carried out.

RESEARCH RESULTS

We found that the use of VENTFORT® in patients with arterial atherosclerosis contributed to the improvement of general well-being, especially in patients with cerebrovascular disorders.

As can be seen from Table 2, the use of VENTFORT® contributed to a significant decrease in the level of total cholesterol in the blood. There was also a tendency towards a reduction of the content of very-low-density lipoproteins, which are the most atherogenic.

The majority of patients have seen an improvement in skin and hair conditions. A significant increase in the strength of the capillary walls was observed in patients with senile purpura after the use of VENTFORT®, as evidenced by the results of the Hess test. The incidence of bleeding spots decreased.

Influence of VENTFORT® on lipid metabolism indicators

Table 2

Indicator	Before treatment	After treatment with general-purpose drugs	After treatment with Ventfort®
Total cholesterol, (mmol/l)	8,6±0,4	7,2±0,5*	6,0±0,7*
Very low-density lipoproteins, (mmol/l)	1,32±0,05	1,13±0,07	0,91±0,07
Triglycerides, (mmol/l)	4,7±0,5	4,3±0,6	4,1±0,6

* P <0.05 –reliable in comparison with the indicator before treatment.

An improvement in the skin condition and an increase in the strength of the walls of the capillaries were observed in patients with senile purpura after the application of VENTFORT®, as evidenced by the results of the Hess test. The incidence of bleeding spots decreased.

Thus, the results of this study indicate the therapeutic efficacy of VENTFORT® and the viability of its use in the complex treatment of atherosclerosis and vascular pathology.

When using VENTFORT®, no side effects, complications, contraindications, or drug dependence were observed.

The studied final form of VENTFORT® is convenient for in-hospital, outpatient, and home use. VENTFORT® can be used for therapeutic and prophylactic purposes in the form of a biologically active food supplement as a part of the complex therapy of vascular atherosclerosis and improvement of microcirculation in various tissues in combination with any means of symptomatic and pathogenetic treatment..

CONCLUSION

The biologically active food supplement VENTFORT® has a regulating effect on the content of cholesterol and blood lipoproteins and improves the vascular wall condition.
VENTFORT® is well tolerated when administered orally, has no side effects, has no contraindications, and can be used as part of the complex treatment and prevention of vascular diseases of various origins.
VENTFORT® is recommended to improve the functions of the vascular wall in atherosclerosis, impaired microcirculation in organs and tissues in various diseases, and the effect of various extreme factors on the body. It is also recommended for the elderly to maintain the function of the vascular system.
Recommended doses:
- For patients with vascular atherosclerosis - orally 10-15 minutes before meals, 1-3 capsules 2-3 times a day for 10-20 days;
- For patients with senile purpura - orally 10-15 minutes before meals, 1-3 capsules 2-3 times a day for 10-30 days;
It is advisable to repeat the course of treatment every 3-6 months

REFERENCES

1. Belousov Y.B., Moiseev V.S., Lepakhin V.K. Clinical Pharmacology and Pharmacotherapy: A Guide for Physicians. - M .: the Universe, 1993 .-- 398 p.
2. Blood disorders in the elderly: Translation from English / Ed. M.J. Denham, I. Chanarin. - M.: Medicine, 1989 .-- 352 p.
3. Hormones and vascular diseases: Translation from English / Ed. R.M. Greenhalga. - M.: Medicine, 1984 .-- 344 p.
4. Korkushko O.V. Cardiovascular system and age. – M.: Medicine, 1983. – 176 p.
5. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
6. Geriatry manual / Ed. D.F. Chebotarev, N.B. Mankovsky. – M.: Medicine, 1982. – 544 p.

RECOMMENDATIONS FOR USE

A complex of peptide fractions obtained from the vessels of young animals. The isolated peptides have a selective effect on various vascular wall cells, normalize cell metabolism, and regulate the functions of the vascular system. It is recommended to take 1-2 capsules of Ventfort® 1-2 times a day with meals. The duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.
Do not use in case of: individual intolerance to the components, pregnancy, or breastfeeding.
No side effects have been identified with the use of Ventfort®.
Store in a dry, dark place at a temperature of +2 to +25 °C. Release form: 20 or 60 capsules of 0.2 g.
Shelf life: 5 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Visoluten®

Report on the results of clinical studies of the biologically active food supplement **Visoluten®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement VISOLUTEN® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the tissues of the eyes of young animals - calves up to 12 months of age or pigs.
VISOLUTEN® is available in capsules with an active substance content of 10 mg.
VISOLUTEN® peptides regulate metabolic processes in the cells of the eye tissues, increase the reserve capabilities of the organ of vision, have a beneficial effect on the adaptation processes of the body in extreme conditions, have antioxidant properties, and regulate the processes of peroxidation in the tissues of the eye. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This allows us to assume the effectiveness of the use of VISOLUTEN® for the restoration of visual functions in case of disorders of various origins. According to experimental data, VISOLUTEN® promotes the normalization of functional and morphological disorders of the organ of vision.
The development of treatment tools that allow for the complete rehabilitation of patients with eye injuries and their consequences, dystrophic diseases of various eyeball structures is an urgent and complex problem in ophthalmology. Hereditary or post-traumatic insufficient vitality of eye tissues often leads to their progressive destruction (1, 2).
Drug treatment of these diseases includes the use of the following drugs (1, 3):
- Vitayodurol, vitafacol;
- Vitamins B1, B6;
- Biostimulants (aloe, FiBS);
- etc.

The clinical study of VISOLUTEN® was carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology from January to August 2011.
A clinical trial of VISOLUTEN® was carried out in patients with dystrophic diseases of the retina of the eye of various etiologies and post-traumatic endothelial-epithelial corneal dystrophies. The study involved 49 patients randomly divided into 2 groups - the control group (20 people) and the primary group (29 patients). The distribution of patients by groups is shown in Table 1.
Patients in the control group received conventional therapy. In addition to conventional treatment, patients of the primary group were prescribed VISOLUTEN® orally 10-15 minutes before meals, 1-3 capsules 2-3 times a day for 30 days, depending on the severity of the pathological process. For post-traumatic visual impairments, VISOLUTEN® was prescribed in the rehabilitation period after surgery. A progressive narrowing of the visual fields decreased visual acuity, degenerative changes in the retina and narrowing of the retinal vessels were registered when examining patients.

Distribution of patients by diagnosis, sex and age.

Table 1

Diagnosis	Age	Group	Male	Female	Total
Retinal dystrophic diseases	51-70	Control	4	6	10
		Primary	8	9	17
Posttraumatic endothelial-epithelial corneal dystrophies	20-43	Control	5	5	10
		Primary	7	5	12
Total:			24	25	49

RESEARCH METHODS

All patients before and after the course of treatment were examined according to a comprehensive clinical program, including, along with the obligatory - traditional methods, methods for diagnosing and clarifying visual impairment, blood flow velocity, the state of the outer and inner layers of the retina, the state of the retinal pigment epithelium.

Traditional examination methods included: a study of visual acuity and visual field, a study of dark adaptation, a study of intracranial pressure, biomicroscopy of the anterior segment of the eyes, deep optical media, biomicro-ophthalmoscopy, stereophthalmoscopy, direct ophthalmoscopy.

Diagnostic and clarifying examination methods included: visocontrastometry, static and multiple central perimetry, color perception study, fundus fluorescence angiography, Doppler sonography, electrophysiological studies.

A general clinical study of blood and urine, a biochemical study of blood on the apparatus «REFLOTRON» (Boehringer Mannheim, Germany) were carried out.

RESEARCH RESULTS

Evaluation of clinical and laboratory functional parameters revealed changes in all parts of the eyeball (iris, lens, vitreous body, optic nerve) in patients with degenerative diseases of the retina, which means generalization of the pathological process with a tendency to progress as the disease progresses.

As a result of the studies, it was found that in the case of application of VISOLUTEN® in addition to the conventional treatment, the maximum therapeutic effect was observed in patients with the initial stages of degenerative changes in the retina. This was manifested in an increase in visual acuity and an improvement in the electrophysiological parameters of the retina, the results of fluorescent angiography, and changes in visual fields (expansion of the peripheral boundaries, reduction or disappearance of paracentral scotomas). The research results are presented in tables 2 and 3.

Influence of VISOLUTEN® on the dynamics of visual acuity in patients with degenerative diseases of the retina.

Table 2

Visual acuity index	Before treatment, (%)	After Treatment with Conventional Methods, (%)	After Treatment with VISOLUTEN®, (%)
0,0 to 0,1	35,7	28,3	16,5
0,2 to 0,8	56,2	61,9	67,8
0,9 to 1,0	8,1	9,8	15,7

So, from the data in Table 2, it can be seen that when additional VISOLUTEN® was included in the treatment regimen for patients of the primary group, visual acuity significantly increased in most patients: the number of patients with visual acuity from 0.9 to 1.0 increased from 8.1% to 15, 7%, and patients with visual acuity from 0.2 to 0.8 - from 56.2 to 67.8%, while the number of patients with visual acuity below 0.1 - from 35.7% to 16.5 %. The pain indicators in the control group indicate the insufficient effectiveness of the conventional treatment: the number of patients with visual acuity from 0.9 to 1.0 after the course of treatment remained practically unchanged, and the number of patients with low visual acuity (from 0.0 to 0.1) decreased slightly - from 35.7% to 28.3%.

These data are consistent with the results of the electrophysiological study shown in Table 3. From the data in Table 3, it can be seen that the electroretinography indices of both the «A» and «B» waves, with the additional inclusion of VISOLUTEN®in the treatment regimen, significantly increase

in comparison with the indicators before treatment and with indicators in the control group and approaching the physiological norm. The indicators in the control group, whose patients received conventional treatment, significantly differ from the before treatment but do not reach the boundaries of the physiological norm.
The use of VISOLUTEN® in post-traumatic keratoconjunctivitis had a stimulating effect on the cornea's reparative regeneration, promoting the formation of more delicate corneal scars, increasing the effectiveness of the treatment by 1.4 times and providing a more stable therapeutic effect in comparison with the results in the control group. The phenomena of blepharospasm, photophobia, and lacrimation in patients receiving VISOLUTEN® disappeared 2.4 times faster than in the control group.

The effect of VISOLUTEN® on electroretinography indicators in patients with degenerative diseases of the retina

Table 3

Indicators		Norm	Before Treatment	After Treatment with Conventional Methods	After Treatment with Visoluten®
Wave «A»	**μV**	30-60	18,6±1,0	24,6±1,6*	33,2±1,5*#
	mS	15-25	19,7±1,3	22,5±2,7	23,1±1,9
Wave «B»	**μV**	225-400	119,7±8,9	178,3±9,4*	216,3±10,3*#
	mS	37-50	57,5±1,9	51,6±1,3	53,2±2,1

* p <0.05 - statistically significant in comparison with the indicator before treatment;
# p <0.05 - statistically significant in comparison with the indicator in the control group.

The appointment of VISOLUTEN® in the postoperative period after keratoplasty and vitreoretinal operations made it possible in 86.7% of cases to prevent postoperative complications and shorten the rehabilitation period.
VISOLUTEN® does not cause side effects, complications, or drug dependence.
The obtained results from the clinical study of the drug indicate the therapeutic efficacy of VISOLUTEN® and the practicality of its use in the complex treatment of patients with dystrophic diseases of the retina and post-traumatic epithelial-endothelial corneal dystrophies, keratoconjunctivitis, as well as in the postoperative period in combination with symptomatic and pathogenetic drugs as an additional agent.

CONCLUSION

Biologically active food supplement VISOLUTEN®has a normalizing effect on the metabolism of the eyeball tissues and helps restore the optical structures of the eye.
VISOLUTEN® is well tolerated when taken orally, has no side effects, and can be widely used as a therapeutic and prophylactic biologically active food supplement.
VISOLUTEN® is recommended for use:
- To patients with degenerative diseases of the retina - orally 10-15 minutes before meals, 1-3 capsules 2-3 times a day for 15-30 days, depending on the severity of the pathological process;
- To patients with post-traumatic corneal dystrophies - orally 10-15 minutes before meals, 2-3 capsules 2-3 times a day for 15-30 days, depending on the severity of the pathological process;
- For prophylactic purposes in people whose professional activity is associated with eye strain, work in dusty and smoky rooms - orally 10-15 minutes before meals, 1 capsule 2 times a day for 15-30 days.
According to indications, a second course of treatment is recommended after 3-6 months.
It is advisable to recommend VISOLUTEN® for therapeutic and prophylactic use and industrial production.

REFERENCES

1. Danilichev V.F., Khavinson V.Kh., Vasilieva L.A. Treatment of peripheral pigmentary tapetoretinal abiotrophy // Ophthalmological journal. - 1992. - No. 3. - S. 174 - 178.
2. Maksimov I.B. Complex peptide correction in microsurgical treatment of eye injuries and their consequences (experimental clinical study): Abstract of the thesis. diss. .... Dr. med. sciences. - M., 1996 .-- 36 p.
3. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.

RECOMMENDATIONS FOR USE

VISOLUTEN® is a complex of peptides obtained from the tissues of the eyes of young animals. The isolated peptides have a selective effect on various cells of the eye’s tissues (retina, lens, cornea), normalize metabolism in cells, and regulate their functions.
In the clinical study, the effectiveness of VISOLUTEN® was established for the complex restoration of the functions of the organ of vision after diseases of various origins, including monetary-dystrophic, in pathological conditions leading to impaired visual function, exposure to extreme environmental factors, including occupational, malnutrition, as well as aging.
VISOLUTEN® instructions: 1-2 capsules or tablets of VISOLUTEN® 1-3 times a day with meals. The duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.
Do not use in case of: individual intolerance to the components, pregnancy, breastfeeding.
No side effects have been identified while using VISOLUTEN®.
Store in a dry, dark place at a temperature from +2 to +25 °C.
Release form: 20 capsules or tablets containing 10 mg of VISOLUTEN®.
Expiration date: 5 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Vladonix®

Report on the results of clinical studies of the biologically active food supplement **Vladonix®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

The biologically active food supplement VLADONIX® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, extracted from the thymus tissue of young animals - calves up to 12 months of age or pigs.
VLADONIX® is available in tablets or capsules with an active ingredient content of 10 mg.
VLADONIX® peptides regulate metabolic processes in the cells of the immune system, restore impaired immunological reactivity, and stimulate regeneration processes if they are suppressed. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This suggests the effectiveness of VLADONIX® for restoring the function of the immune system in various pyoinflammatory and other diseases characterized by the suppression of the immune status of patients.
We know that various physical, chemical, and biological factors, depending on the duration or intensity of their impact on the human body, can weaken adaptive and compensatory mechanisms and cause profound disorders in various links of the immune defense system (2, 3).
Pathological disorders in the immune system usually contribute to a long course of the underlying disease with a tendency to relapse, a decrease in the body's resistance to infection, and the development of severe complications.
Among the means that contribute to the restoration of immunological reactivity, immunomodulators of various origins are considered: enzyme preparations (trypsin, lysozyme), bacterial polysaccharides (pyrogenal, prodigiosan), yeast polysaccharides (zymosan, glucans, propermil, dextrans), vaccines (BCG), nucleic acid medication (sodium nucleinate), purine and pyrimidine derivatives, levamisole, diucifon, traditional medicine and many others (1, 2).
Clinical trials of VLADONIX® took place from November 2005 to February 2006 at the Medical Center of the Saint Petersburg Institute of Bioregulation and Gerontology of the Northwest Branch of the Russian Academy of Medical Sciences, in patients exposed to long-term influence of low doses of ionizing radiation, including oncological patients after radiation and chemotherapy.
The primary group consisted of 42 patients (23 men, 19 women), who, in addition to conventional treatments, were prescribed VLADONIX® 1-3 capsules 2-3 times a day before meals for 15-20 days, depending on the severity of their immune status disorders. Patients in the control group received only general-purpose drugs. The age of patients in both groups ranged from 34 to 65 years. The distribution of patients by nosological forms, sex, and age is presented in Table 1.

Distribution of patients by nosological forms, sex and age

Table 1

Diagnosis	Age (years)	Male		Female		Total	
		Control group	Primary group	Control group	Primary group	Control group	Primary group
Condition after exposure to low doses of ionizing radiation	34-51	12	14	6	8	18	22
Condition after radiation and chemotherapy in cancer patients	45-65	7	8	9	12	16	20
Total		19	22	15	20	34	42

RESEARCH RESULTS

VLADONIX® efficiency was assessed by the changes in patients' complaints and by a number of objective indicators: general clinical examination of blood and urine, immunological examination of peripheral blood (the number of T- and B-lymphocytes was determined by the method of immunofluorescence with monoclonal antibodies obtained to the differentiation antigens of lymphocytes CD3, CD4, CD8, CD20; the content of immunoglobulins of various classes - by the method of radial immunodiffusion in gel according to Mancini; functional activity of T-lymphocytes - in the reaction of inhibition of lymphocyte migration (RTML) with ConA).

Studies have shown that 92% of people living in an ecologically unfavorable territory have disorders in the immune status, manifested in a decrease in the number of CD3+, CD4+ cells, with a slight increase in lymphocytes with the CD8+ phenotype, which indicates a reduction in the level of immunoreactivity (CD4+/CD8+). The results of RTML with ConA characterize a decrease in the functional activity of T-lymphocytes (mainly CD8+, i.e., T-suppressors/killers). The content of CD20+ - cells, representing a subpopulation of B-lymphocytes, did not significantly differ from normal values. Still, an increase in the amount of immunoglobulins M and G in the blood serum was observed (Table 2).
It should be noted that the quantitative indicators of the content of CD3+ and CD4+ - cells are characteristic of the lower limits of physiological fluctuations in their number in patients of this age, which may indicate the weakening and premature aging of the immune system. As a rule, patients with a secondary immunodeficiency state had a pronounced asthenic syndrome and significant changes in the cardiovascular system.

Influence of VLADONIX® on indicators of cellular and humoral immunity in individuals exposed to low doses of ionizing radiation

Table 2

Indicators	Before treatment	After treatment with	After treatment with
Leukocytes, x10⁹/l	5,0±0,2	5,4±0,1	5,6±0,1
Lymphocytes, % **x10⁹/l**	26,2±2,6 1,51±0,08	31,4±2,4 1,64±0,05	35,1±2,1 1,87±0,05
CD3⁺, % **x10⁹/l**	46,5±2,3 1,53±0,09	51,9±2,2 1,65±0,07	55,7±2,6* 1,86±0,05*
CD4⁺, % **x10⁹/l**	28,5±2,8 0,41±0,01	30,8±2,1 0,49±0,07	34,6±2,0* 0,67±0,09*
CD8⁺, % **x10⁹/l**	26,4±1,5 0,43±0,05	25,7±1,6 0,42±0,03	24,9±1,8 0,46±0,07
CD4⁺/CD8⁺	1,1	1,2	1,4*
CD20⁺, % **x10⁹/l**	12,3±0,6 0,18±0,01	12,0±0,4 0,21±0,01	12,0±0,7 0,20±0,01
RTML, %	88,1±5,4	76,2±4,8*	70,4±4,9*
IgM, (g/l)	1,82±0,06	1,72±0,05	1,66±0,06
IgG, (g/l)	15,7±1,3	15,6±1,6	15,3±1,7
IgA, (g/l)	2,2±0,1	2,0±0,1	2,1±0,3

* P <0.05 –reliable in comparison with the indicator before treatment.

The results of the studies conducted convincingly indicate that VLADONIX® is an effective remedy for correcting secondary immunodeficiencies that develop in response to exposure to extreme factors.
The use of VLADONIX® in combination with symptomatic agents made it possible to normalize the impaired parameters of the immune system in 78% of cases.
As follows from the data presented above, the most significant effect from the use of VLADONIX® was observed in relation to subpopulations of T-lymphocytes and their functional activity (a significant increase in the content of CD3+ and CD4+ lymphocytes, normalization of the CD4+/CD8+ ratio). A less distinct reaction took place on the part of the B-system of the immune system, probably due to its greater conservatism.
After the course of treatment with VLADONIX®, patients who received small doses of ionizing radiation noted a significant improvement in their general condition and a decrease in the severity of the asthenic syndrome, which always accompanies secondary immunodeficiencies.
In oncological patients, after radiation and chemotherapy, an accelerated normalization of immunological parameters was noted compared to the control group, which led to an improvement in overall well-being

and a decrease in the incidence of complications. It is noteworthy that the patients of the primary group tolerated radiation and chemotherapy more easily. All were able to complete the entire course of radiation therapy (in the control group - 79%).

CONCLUSION

Clinical trials have shown that VLADONIX® contributes to the normalization of cellular immunity indicators and stimulates tissue regeneration processes in the event of their suppression. It does not cause side effects, complications, or drug dependence. It can be used for therapeutic and prophylactic purposes in combination with any means of symptomatic and pathogenetic therapy used to correct secondary immunodeficiency states (immunomodulators, adaptogens, vitamins, etc.).
VLADONIX® is recommended to be used to accelerate the restoration of the functions of the immune system after infectious diseases, radiation, and chemotherapy, exposure of the body to various extreme factors (including ionizing and microwave radiation). It is also recommended for the elderly to maintain the functions of the immune system.
It is recommended to take VLADONIX® 10-15 minutes before meals, 1-3 capsules 2-3 times a day for 20-30 days.
A second course is desirable in 3-6 months.
There were no side effects, complications, contraindications, or drug dependence observed during the clinical study when using VLADONIX®.

REFERENCES

1. Drannik G.N., Grinevich Y.A., Disik G.M. Immunotropic medication. – Kiev Zdorov'ya, 1994. – 288 p.
2. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO "Gamta", 1993.
3. Novikov V.S., Smirnov V.S. Immune physiology of extreme conditions. – SPb.: Nauka, 1995. – 172 p.
4. Schek M.G., Kosinets A.N., Adamenko G.P. Immunological aspects of surgical infection. – Vitebsk: B. i., 1994. – 140 p.

RECOMMENDATIONS FOR USE

The drug contains a complex of peptide compounds isolated from the thymus of healthy calves aged between 6-12 months. The peptides included in VLADONIX® selectively act on the cells of the immune system, regulating its functions and normalizing cell metabolism. The drug will help comprehensively restore the immune system after past illnesses, after being exposed to extreme environmental factors, unbalanced nutrition, aging, and pathological conditions, as a result of which the functions of the immune system are impaired.
Depending on the goals (prevention, treatment) and the severity of pathological manifestations, VLADONIX® is taken for 10-20 days.
Adults: 1-2 capsules 1-2 times a day with meals. The duration of admission is 30 days. Do not use in case of: individual intolerance to the components, during pregnancy or breastfeeding. No side effects have been identified.
It is recommended to repeat the course of treatment after 6 months. Store in a dry, dark place at a temperature of +2 to +25 oC. Release form: 20 or 60 capsules of 0.2 g.
Shelf life: 5 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Glandokort®

Report on the results of clinical studies of the biologically active food supplement **Glandokort®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement GLANDOKORT® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, extracted from adrenal tissues of young animals - calves notolder than 12 months of age or pigs.
GLANDOKORT® is available in capsules with an active substance content of 10 mg.
Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. GLANDOKORT® peptides regulate metabolic processes in the adrenal cortex cells, increase their reserve capacity, and have a beneficial effect on the adaptation processes of the body in extreme conditions. They also possess antioxidant properties and regulate the peroxidation processes in the tissues of the adrenal glands. This allows us to assume the effectiveness of GLANDOKORT® for restoring the functions of the endocrine system in case of their disorders of various origins, including with prolonged exposure to stress factors, with aging.
Age-related or stress-induced decrease in the functional activity of the adrenal glands is one of the causes of dyshormonal and maladaptive disorders (3, 4).
Drug treatment of these diseases and pathological conditions includes the use of the following drugs (1, 2):
- Glucocorticoids - prednisolone, hydrocortisone;
- Mineralocorticoids;
- Adaptogens (ginseng, extracts of Eleutherococcus, Leuzea, Rhodiola rosea, tinctures of aralia, zamanihi, saparal, pantocrine).

CLINICAL CHARACTERISTICS OF PATIENTS

A clinical study of the effectiveness of the use of GLANDOKORT® was carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology in the period from April to November 2011.
The study involved 36 patients aged 37 to 62 years, including 25 men and 11 women, with chronic adrenal cortex insufficiency and conditions after prolonged exposure to occupational and psycho-emotional stress. Patients of the primary group received complex treatment using adaptogens (conventional medicine) and GLANDOKORT® 1 capsule 2 times a day with meals for 30 days.
The control groups consisted of 26 patients with similar diseases who were prescribed conventional treatment with adaptogens. Patients receiving hormone therapy were excluded from the study.
Patients suffering from a chronic adrenal cortex insufficiency or under occupational or psycho-emotional stress for a long time complained of general weakness, decreased appetite, headaches, sleep disturbances, increased irritability, and apathy.

RESEARCH METHODS

The effectiveness of GLANDOKORT® was assessed subjectively by studying the dynamics of patients' complaints and objective indicators. A biochemical blood test was carried out for a general clinical study of blood and urine. The content of hormones (cortisol, insulin) in the blood serum was determined by radioimmunological methods. Using various biochemical processes, we defined the content of adrenaline and aldosterone in the blood plasma. The level of excretion of 17-ketosteroids was found in the urine.

RESEARCH RESULTS

It was found that the use of GLANDOKORT® contributed to the improvement of the general condition of patients in the studied group. Patients noted increased physical and mental performance, improved mood, and sleep.

Influence of GLANDOKORT® on the level of adrenal hormones in patients with chronic adrenal cortex insufficiency TTable 1

Indicator	Norm	Before treatment	After treatment with conventional methods	After treatment with Glandokort®
Aldosterone in blood plasma, (pg/ml)	7,5-150	14,7±1,2	26,2±1,6	38,5±1,3*,**
17-ketosteroids common in urine, (µmol/day)	17-70	19,8±1,6	38,2±2,4	46,3±2,1*

* p <0.05 - significant in comparison with the indicators before treatment;
** p <0.05 - significant in comparison with the indicators in the control group.

Patients with chronic adrenal cortex insufficiency, taking GLANDOKORT®, showed positive results. There was a restoration of the metabolic activity of the reticular adrenal zone, accompanied by an increase in the production of aldosterone and 17-ketosteroids, the content of which increased to the average values of the norm (Table 1).

Effect of GLANDOKORT® on plasma levels of cortisol and adrenocorticotropic hormone in subjects exposed to prolonged occupational or psycho-emotional stress. Table 2

Indicator	Norm	Before Treatment	After treatment with conventional methods	After treatment with Glandokort®
Cortisol (nmol/L)	250-750	287,5±18,5	311,4±21,4	431,4±25,7*,**
ACTH (pg/ml)	10-80	14,2±1,1	17,4±1,3	28,6±1,1

* p<0.05 - significant in comparison with the indicators before treatment.

The use of GLANDOKORT® in persons exposed to prolonged exposure to professional or psycho-emotional stress contributed to stabilizing the hormonal status, which indicates the leveling of maladjustment disorders and catabolic reactions (Table 2). The content of cortisol and adrenocorticotropic hormone (ACTH) before the start of treatment was noted at the lower limit of the norm, which indicated the depletion of the reserves of the adrenal cortex—after complex therapy using GLANDOKORT®, the level of cortisol and ATKG in the blood plasma returned to normal. These changes were correlated with improvements in subjective scores.
No side effects, complications, or drug dependence were identified when using GLANDOKORT®.

CONCLUSION

Biologically active food supplement GLANDOKORT®has a normalizing effect on the functional activity of adrenal cortex cells.
GLANDOKORT® is well tolerated when taken orally, has no side effects, and can be used as a therapeutic and prophylactic biologically active food supplement.
GLANDOKORT® is recommended for use orally with meals, 1-2 capsules two times a day for 30 days, for patients with impaired adrenal cortex function or prolonged exposure to professional or psycho-emotional stress.
It is recommended to repeat the course in 3-6 months.

REFERENCES:

1. Belousov Y.B., Moiseev V.S., Lepakhin V.K. Clinical Pharmacology and Pharmacotherapy: A Guide for Physicians. - M .: the Universe, 1993 .-- 398 p.
2. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”,

1993.
3. Geriatric manual / Ed. D.F. Chebotarev, N.B. Mankovsky. – M.: Medicine, 1982. – 544 p.
4. Tepperman J., Tepperman H. Physiology of metabolism and the endocrine system: Translation from English - M .: Mir, 1989 .-- 656 p.

RECOMMENDATIONS FOR USE:
GLANDOKORT® is a complex of peptides obtained from the adrenal glands of young animals. The isolated peptides have a selective effect on adrenal cells, normalize their metabolism, and regulate the functions of the endocrine system.
The effectiveness of GLANDOKORT® was confirmed in a clinical study. It proved its usefulness in the complex treatment of patients with dysfunction of the adrenal cortex, with prolonged exposure to professional or psycho-emotional stress, to restore the functions of the endocrine system after diseases of various origins, when exposed to extreme environmental factors, malnutrition, as well as aging.
Glandokort® instructions: 1-2 capsules or tablets with meals 1-2 times a day. The duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.
Do not use in case of: individual intolerance to the components, pregnancy, breastfeeding.
No side effectshave been identified during the use of GLANDOKORT®.
Store in a dry, dark place at a temperature from +2 to +25 °C.
Release form: 20 capsules or tablets containing 10 mg of GLANDOKORT®.
Expiration date: 3 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Gotratix®

Report on the results of clinical studies of the biologically active food supplement **Gotratix®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement GOTRATIX® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the tissues of the triceps muscle of young animals - calves notolder than 12 months of age or pigs.
GOTRATIX® is available in capsules with an active substance content of 10 mg.
Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are extracted. GOTRATIX® peptides regulate metabolic processes in muscle cells, increase their reserve capacity, have a beneficial effect on the adaptation processes of the body in extreme conditions, and have antioxidant properties, regulating the processes of peroxidation in muscle tissues. This allows us to assume the effectiveness of the use of GOTRATIX® for the restoration of muscle functions during intense physical activity and sports.
To improve the physical performance of athletes and their adaptation to increased physical and psycho-emotional stress, various means and methods of pharmacological and, more recently, genetic correction are very actively used (Seifulla, 1999; Yakimov, 2001). It is incontrovertibly proven that athletes using prohibited pharmacological drugs cannot demonstrate stable high athletic form for a long time since they experience physiological breakdowns under increased pressure (Semenov et al., 2002). The danger is aggravated by the fact that many new stimulating substances appear, the doping effect of which is «masked» by various food and vitamin supplements (Mikhailov, 2006).
Therefore, the problem of early detection of the negative consequences of taking modern doping substances is not the only issue. The development of a complex of methods for bioregulation of physiological reserves of highly qualified athletes to effectively prevent physical maladjustment in the dynamics of the training cycle also poses a problem.
Maintaining the reserve capacity of the muscular system is an urgent problem for people who are engaged in a feasible physical culture, including the elderly.

CLINICAL CHARACTERISTICS OF PATIENTS

The effectiveness of using GOTRATIX® was determined by the dynamics of changes in speed-strength qualities using tests: measurement of maximum wrist dynamometry (right and left hand), long jump from a standing position.
Endurance was determined using a test that is an interpretation of the Harvard step test. Flexibility was determined using an exercise: bending forward while standing on a gymnastic bench.

RESEARCH RESULTS

The use of GOTRATIX® contributed to improving the general condition of patients in the studied group. Patients noted an increase in physical performance. The table presents a comparative analysis of the indicators of the primary and control groups during two tests, in which the examined control groups trained according to the usual plan, and the primary group took GOTRATIX®in addition to the usual workout. The interval between tests was two months.
The table shows that the indicators of speed-strength qualities of dynamometry and long jump in the primary group significantly increased compared to the initial indicators. In contrast, they remained at the same level in the examined control group. The indicators of the step test and flexibility in the subjects taking GOTRATIX® tended to increase in comparison with the initial data but did not differ significantly.
While taking GOTRATIX®, the subjects noted less fatigue during training than the initial level, better workability, and faster muscle recovery after exercis

Influence of GOTRATIX® on the dynamics of parameters of physical qualities in men, M ± m

Table

№ Test	Test / Group	Dynamometry		Long Jump, cm	Step-Test, 1 step	Flexibility Test, cm
		Right hand, kg	Left hand, kg			
1	Control Group, n = 17 Primary Group, n = 22	46±1,4 47±2,1	43±1,3 42±1,7	212±6 215±4	53±6,3 55±3,1	6,3±2,1 7,0±1,1
2	Control Group, n = 17 Primary Group, n = 22	47±1,6 53±3,9*	45±1,8 48±1,4*	219±6 231±3*	57±7,5 58±6,8	7,5±1,7 9,2±2,1

* - The differences are statistically significant (p <0.05): the second test compared to the first in the corresponding group.

Thus, the use of GOTRATIX® contributed to an increase in the effectiveness of physical exercises, less fatigue.
In using GOTRATIX®, no side effects, complications, or drug dependence were identified.

CONCLUSION

Biologically active food supplement GOTRATIX® has a normalizing effect on the functional activity of muscle cells.
GOTRATIX® is well tolerated when taken orally, has no side effects, and can be used as a therapeutic and prophylactic biologically active food supplement.
GOTRATIX® is recommended for people of different ages with increased physical activity, including sports. It is taken orally with meals, 1-2 capsules 2-3 times a day for 30 days.
According to indications, a second course of treatment should be carried out after 3-6 months.

REFERENCES

1. Buresh L., Bureshova O., Houston J. Methods and main experiments for the study of the brain and behavior. - M., 1991. -- 399 p.
2. Verbitsky E.V. Psychophysiology of anxiety. - Rostov-on-Don: Publishing house of the Russian State University. - 2003. - 192 p.
3. Vovk S.I. Features of long-term dynamics of fitness // theory and practice of physical culture. - 2001, No. 2. - P. 28-31.
4. Ivko O.M. The influence of sports injuries on the quality of life of sports veterans in old and senile age // Abstract of the thesis ... Candidate of Biological Sciences: 14.00.53- SPb, 2007. - 25 p.
5. Korkushko O.V., YaroshenkoYu.T. Maximum oxygen consumption in men depending on age and level of physical activity // Human Physiology. - 1996. - T.22, No. 4. - P. 100-103.
6. Kulinenkov O.S. Pharmacological assistance to an athlete: correction of factors limiting sports performance // M, 2006. - 240 p.
7. Lysenko A.V. Arguments in favor of the use of biologically active peptides in the practice of sports pharmacology // Theory and practice of physical culture. - 2004. - No. 10. - P. 25-29.

RECOMMENDATIONS FOR USE

GOTRATIX® is a complex of peptides obtained from the muscles of young animals. The isolated peptides have a selective effect on muscle cells, normalize their metabolism, and regulate the functions of the muscular system.

In a clinical study, the use of GOTRATIX® was established to increase the effectiveness of intense physical activity, including during sports, to restore the functions of the muscular system after diseases of various origins, under the influence of extreme environmental factors, malnutrition, as well as aging.

GOTRATIX® is recommended: 1-2 capsules or tablets 2-3 times a day with meals. The duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.

Do not use in case of: individual intolerance to the components, pregnancy, breastfeeding.

No side effectshave been identified when using GOTRATIX®.

Store in a dry, dark place at a temperature from +2 to +25 °C.

Release form: 20 capsules or tablets containing 10 mg of GOTRATIX®.

Expiration date: 3 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Zhenoluten®

Report on the results of clinical studies of the biologically active food supplement **Zhenoluten®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement ZHENOLUTEN® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the tissues of the triceps muscle of young animals - calves notolder than 12 months of age or pigs.
ZHENOLUTEN® is available in capsules with an active substance content of 10 mg.
ZHENOLUTEN® peptides regulate metabolic processes in ovarian cells, increase their reserve capacity, have a beneficial effect on the body's adaptation processes in extreme conditions, and have antioxidant properties, regulating the peroxidation processes in ovarian tissues. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This allows us to assume the effectiveness of the use of ZHENOLUTEN® to restore the functions of the reproductive system in women with disorders of various origins.
Age-related or pathological changes in ovarian function are characterized by the development of a complex symptom-complex with the manifestation of neuropsychic, vasomotor, and metabolic-endocrine disorders, combined into the concept of «climacteric syndrome» (1, 4, 5). These disorders occur in women over the age of 45; they significantly reduce their quality of life.
Currently, non-hormonal and hormonal medications are used to treat menopause and ovarian wasting syndrome, many of which have severe contraindications and side effects (2, 3):
- Sympatholytics - reserpine, obsidan;
- Anticholinergics - belladonna tincture;
- Antihistamines - tavegil, suprastin;
- Tranquilizers - tazepam;
- Vitamins B1, B6, E;
- Steroid estrogens - estradiol dipropionate, folliculin, ethinylestradiol, estriol;
- Gestagens (progestins) - progesterone, turinal, norkolut, premalut-nor, pregnin;
- Combined estrogen-gestagenic drugs - biseurin, non-ovlon;
- etc.

CLINICAL CHARACTERISTICS OF PATIENTS

A clinical study of the efficacy of ZHENOLUTEN® was carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology from April to November 2011.
The clinical study involved 39 women aged 45 to 53 years with a mild to moderate climacteric syndrome diagnosis and 28 women aged 38 to 43 years diagnosed with the ovarian wasting syndrome (early climacteric syndrome).
Patients complained of hot flashes to the head and upper body, accompanied by increased sweating, headache, and surges in blood pressure, pain in the heart, chills, tachycardia attacks at rest, a tendency to fainting, nausea, a feeling of «sinking» of the heart, dizziness, and weakness. Psychoemotional disorders were most often manifested by irritability, tearfulness, anxiety, sleep disturbances, decreased memory and attention, rapid fatigue, and decreased physical and mental performance. Patients noted an increase in the incidence of respiratory infectious diseases.
During laboratory examination, the patients were found to have hormonal disorders characterized by increased levels of FSH and LH in the peripheral blood in patients with climacteric syndrome. Moreover, in patients diagnosed with ovarian wasting syndrome, an increase in the level of FSH and LH was noted several times. It was accompanied by a significant decrease in estradiol content in the peripheral blood. General clinical and biochemical parameters in the blood did not go beyond the age norm.
All patients were divided into 4 groups: 2 control and 2 primary in accordance with the diagnoses. Patients in both control groups received conventional therapy, which did not include hormonal drugs. In addition to conventional treatment, patients of both main groups received ZHENOLUTEN® 1 capsule 2 times a day with meals for 30 days.
All patients were divided into 4 groups: 2 control and 2 primary following the diagnoses. Patients in both control groups received conventional therapy, which did not include hormonal drugs. In addition to conventional treatment, patients of both primary groups received ZHENOLUTEN® 1 capsule 2 times a day with meals for 30 days.

RESEARCH METHODS

The patients' complaints were assessed in progression, a general clinical examination of blood and urine, a biochemical study of blood on the REFLOTRON apparatus (Boehringer Mannheim, Germany) were carried out. Ultrasound examination of the ovaries was performed using an ultrasound machine (ALOKA, Japan). The content of hormones (FSH, LH, and estradiol) in the blood serum was determined by radioimmunoassay. The radioactivity of the samples was counted on a «Tracor Analytic 1285» counter (USA-Holland).

RESEARCH RESULTS

It was found that the use of ZHENOLUTEN® in patients with mild and moderate climacteric syndrome contributed to an improvement in the general condition, which was manifested in a decrease in the number of hot flashes, improved sleep, appetite, and increased efficiency (Table 1).

Dynamics of subjective indicators in patients with climacteric syndrome.

Table 1

Indicator	Number of Patients. %		
	Before Treatment	After Treatment with Conventional Methods (Control Group)	After Treatment with ZHENOLUTEN® (Primary Group)
Hot flushes in the head and upper body.	72,0	55,1*	31,8*#
Increased sweating.	67,8	50,7*	29,6*#
Fast fatiguability.	68,8	51,3*	31,4*#
Reduced performance.	81,6	53,1*	32,6*#
Irritability.	91,8	54,2*	33,3*#

*p <0.05 compared with the indicator in patients before treatment;
# p <0.05 compared with the indicator in patients after treatment with conventional methods.

In laboratory studies, after the application of ZHENOLUTEN®, a significant decrease in the content of FSH and LH was noted, which caused an increase in the LH / FSH index to the lower limits of age-related physiological fluctuations (Table 2).
The noted changes in the hormonal status of patients while taking ZHENOLUTEN® correlate with clinical indicators. They indicate the restoration of the adequate adaptive response of the aging organism in response to an age-related decrease in ovarian function.

Effect of ZHENOLUTEN®on the content of pituitary hormones in blood serum of patients with climacteric syndrome.

Table 2

Indicator	Norm	Before Treatment	After Treatment with Conventional Drugs (Control Group)	After Treatment with ZHENOLUTEN® (Primary Group)
FSH, (IU / ml)	1,5-45	89,3±3,5	71,6±6,3*	46,8±3,9*#
LH, (IU / ml)	2-17	28,1±1,9	25,7±2,4	16,4±1,4*#

* p <0.05 - statistically significant compared with the indicator before treatment.
# p <0.05 - statistically significant in comparison with the indicator in patients of the control group.

In patients with ovarian depletion syndrome, the use of ZHENOLUTEN® and conventional therapy in 67% of cases normalized the menstrual cycle and helped reduce the astheno-neurotic manifestations of the disease.

Effect of Zhenoluten®on the content of pituitary hormones in blood serum of patients with ovarian wasting syndrome.

Table 3

Indicator	Norm	Before Treatment	After Treatment with Conventional Drugs (Control Group)	After Treatment with Zhenoluten® (Primary Group)
FSH, (IU / ml)	1,5-45	114,6±7,8	87,2±5,4*	56,4±2,9*#
LH, (IU / ml)	2-17	47,3±2,6	38,6±3,9	28,5±2,1*#
Estradiol, (pmol / l)	110-734	51,1±2,6	68,3±3,1*	88,2±4,1*#

* p <0.05 - significant compared with the indicator before treatment;
# p <0.05 - significant compared with the indicator in patients of the control group.

Laboratory data indicate a trend towards normalization of the ratio of hormones FSH, LH, and estradiol (Table 3).
Analysis of this data allows us to conclude that ZHENOLUTEN® has a normalizing effect on cellular metabolism in ovarian tissues, promotes the formation and maturation of follicles, and the restoration of the reproductive system functions in women.
Thus, the results obtained indicate the therapeutic efficacy of ZHENOLUTEN® and the advisability of its use in the complex treatment of patients of different ages with menopause and ovarian depletion syndrome.
When using ZHENOLUTEN®, no side effects, complications, or drug dependence were revealed.
ZHENOLUTEN® can be used for therapeutic and prophylactic purposes in the form of a biologically active food supplement combined with any means of symptomatic and pathogenetic therapy used to treat menopausal syndrome and ovarian wasting syndrome.

CONCLUSION

Biologically active food supplement ZHENOLUTEN® has a normalizing effect on the functional activity of ovarian cells.
ZHENOLUTEN® is well tolerated when taken orally, has no side effects, and can be used as a therapeutic and prophylactic biologically active food supplement.
ZHENOLUTEN® is recommended for use in patients with menopausal syndrome and ovarian depletion syndrome orally with meals, 1-2 capsules 2 times a day for 30 days.
According to indications, a second course of treatment should be carried out after 3-6 months.

REFERENCES

1. Bodyazhina V.I., Smetnik V.P., Tumilovich L.G. Non-Operative Gynecology: A Guide for Physicians. - M.: Medicine, 1990. -- 544 p.
2. Belousov Y.B., Moiseev V.S., Lepakhin V.K. Clinical Pharmacology and Pharmacotherapy: A Guide for Physicians. - M.: the Universe, 1993. -- 398 p.
3. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
4. Geriatric manual / Ed. D.F. Chebotarev, N.B. Mankovsky. – M.: Medicine, 1982. – 544 p.
5. Tepperman J., Tepperman H. Physiology of metabolism and the endocrine system: Translation from English - M.: Mir, 1989. -- 656 p.

RECOMMENDATIONS FOR USE

ZHENOLUTEN® is a complex of peptides obtained from the ovaries of young animals. The isolated peptides have a selective effect on ovarian cells, normalize metabolism in ovarian cells, and regulate the functions of the reproductive system in women.
In a clinical study, the effectiveness of ZHENOLUTEN® was established in the complex treatment of patients with the climacteric syndrome, ovarian depletion syndrome, and to restore the functions of the reproductive system in women after diseases of various origins under the influence of extreme environmental factors, malnutrition, as well as aging.
It is recommended to take ZHENOLUTEN® 1-2 capsules or tablets 1-2 times a day with meals. The duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.
Do not use in case of:individual intolerance to the components, pregnancy, breastfeeding.
No side effectshave been identified when using ZHENOLUTEN®.
Store in a dry, dark place at a temperature from +2 to +25 °C.
Release form: 20 capsules or tablets containing 10 mg of ZHENOLUTEN®.
Expiration date: 3 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Libidon®

Report on the results of clinical studies of the biologically active food supplement **Libidon®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement LIBIDON® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the tissues of the triceps muscle of young animals - mature bulls.
LIBIDON® is available in the form of capsules with an active substance content of 10 mg.
LIBIDON® peptides regulate metabolic processes in the prostate gland cells, increase their reserve capacity, have a beneficial effect on the adaptation processes of the body in extreme conditions, have antioxidant properties, and regulate the processes of peroxidation in the tissues of the prostate. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This allows us to assume the effectiveness of the use of LIBIDON® to restore the functions of the prostate gland in men of different ages with disorders of various origins.
Diseases of the prostate gland currently occupy an important place among urological pathology, tend to increase the incidence, and acquire an ever-increasing social significance (1, 3). According to a number of authors, more than 70% of men over the age of 50 suffer from prostate diseases, including benign prostatic hyperplasia and oncological diseases. Thus, the search for new effective and safe agents for preventing and treating prostate diseases is an urgent task.
In the conservative treatment of patients with prostate diseases, taking into account the pathogenetic mechanisms, the following traditional drugs of various directions of action are mainly used (2):
- Antibacterial and anti-inflammatory action - antibiotics and sulfa drugs;
- Normalization of microcirculation - trental, galidor, escuzan;
- Stimulation of metabolic processes - streptokinase, raveron;
- Antispasmodic action - no-shpa, baralgin;
- Normalization of the level of sex hormones - methyltestosterone, sustanon-250;
- Correction of immunopathological reactions - prodigiosan, pyrogenal, levamisole, tavegil, fenkarol.
- etc.

CLINICAL CHARACTERISTICS OF PATIENTS

A clinical study of the effectiveness of the use of LIBIDON®was carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology in the period from March to November 2011.

Distribution of patients by nosological forms and age. Table 1

Diagnosis	Age	Number of Patients
Chronic prostatitis	38-49	28
Benign prostatic hyperplasia	51-65	20
Total:		48

* p <0.05 - significant compared with the indicator before treatment;
# p <0.05 - significant compared with the indicator in patients of the control group.

Clinical trials were carried out in 48 patients aged 38 to 65 years with a diagnosis of benign prostatic hyperplasia (BPH) and chronic prostatitis (Table 1), who, in addition to conventional therapy, were prescribed LIBIDON®: orally 1 capsule 2 times a day with meals for 30 days. The control groups consisted of 22 similar patients who received only conventional treatment.

RESEARCH METHODS

The effectiveness of treatment was assessed based on the dynamics of patients' complaints, general clinical examination of blood and urine, biochemical blood study on the REFLOTRON apparatus (Boehringer Mannheim, Germany), and blood coagulograms before and after the end of treatment. Using the device «UROFLOUKOMPAKT» (Wiest, Germany), the maximum, average rate and time of urination, the time to reach the maximum rate of urination, and the fluorometric index were assessed. The degree of abdominal pressure during urination and the nature of the urine stream was expressed

in points from 1 to 5 (1 - the norm, 5 - the most significant changes in the indicator).
A palpation assessment of the prostate gland, a laboratory study of its secretion, and a more in-depth analysis of the state of copulatory function were performed along with the studies mentioned above. Ultrasound examination of the prostate was conducted using a portable ultrasound machine (SHIMADZU, Japan).

RESEARCH RESULTS

When evaluating the treatment results with LIBIDON® for chronic prostatitis, the primary attention was paid to clinical criteria. At the end of treatment, the pain completely disappeared in 64.0% and significantly decreased in 32.7% of patients presenting corresponding complaints. In 3.3% of patients, the treatment did not give the expected effect, and the dynamics of pain were not observed.
Of the number of patients suffering from sexual dysfunction, 44.4% indicated their complete recovery, and 41.8% noted an improvement. The positive effect of the drug was manifested in improving the quality of erection, enhancing orgasms, and eliminating their pain. An increase in the duration of intercourse was also noted. By the end of treatment, 37.1% of patients reported libido recovery.
Pollakiuria (increased frequency of urination) altogether ceased to bother 87.5% of patients. The need to urinate at night has disappeared.
Stranguria (difficulty urinating) ceased to bother 80.7% of patients, 15.9% noted an increase in the urine stream and relief of the act of urination.
Summary information on the change in the act of urination in patients with chronic prostatitis after treatment with LIBIDON® is presented in Table 2.
Palpation of the prostate gland through the rectum revealed a tendency to restore its size and consistency after complex treatment with LIBIDON®. At the same time, areas of compaction disappeared, and the study itself became painless. The observed decrease in the prostate gland size, regarded as a result of a decrease in the edema of the interstitial tissue and indicating the elimination of the activity of the inflammatory process in it, was also confirmed by the results of ultrasound diagnostics.
Thanks to the restoration of the function of the prostate gland under the influence of LIBIDON®, an improvement in the properties of its secretion was observed. This provided an increase in the content of motile spermatozoa in the ejaculation by 11.8%. Decreased leukocytes confirmed a decrease in the inflammatory process activity in the ejaculation, prostate secretions, and urine. At the same time, a reduction in the content of cells of desquamated epithelium in the test material was observed.
The dynamics of the study results in patients with prostate adenoma before and after the course of treatment with LIBIDON® is presented in Table 3.

The influence of LIBIDON® on the state of urodynamics in patients with chronic prostatitis

Table 2

Indicator	Before Treatment	After Treatment with Conventional Methods	After Treatment with Libidon®
Average urination rate, (ml/sec)	17,3±1,2	19,8±1,6	23,5±2,4*
Maximum speed of urination, (ml/sec)	22,1±2,3	24,4±2,1	26,5±3,1
Time to reach the maximum urination rate, (ml/sec)	3,6±0,2	2,8±0,1	1,5±0,1*

* p <0.05 - significant compared with the indicator before treatment.

The influence of LIBIDON® on the state of urodynamicsin patients with benign prostatic hyperplasia.

Table 3

Indicator	Before Treatment	After Treatment with Conventional Methods	After Treatment with Libidon®
Time of urinary retention	4,6±0,3	3,2±0,1*	2,5±0,1*
Number of urinations: **- daytime** **- nighttime**	 8,4±0,5 3,1±0,1	 7,1±0,2* 2,8+0,1	 6,3±0,1* 2,6+0,1
Abdominal pressure (measured in points)	3,2	2,8	2,4
The nature of the stream of urine, (measured in points)	3,3	2,6*	2,3*
Average urination rate, (ml/sec)	11,3±1,2	14,2±1,4	17,5±1,6*
Maximum speed of urination, (ml/sec)	16,1±2,3	18,2±1,9	20,5±2,1
Time to reach the maximum urination rate, (ml/sec	6,6±0,3	5,3±0,1*	4,5±0,2*

* p <0.05 — significant compared to the values before treatment.

The condition of patients with BPH after treatment with LIBIDON® was characterized by an improvement in subjective and objective indicators of urodynamics. An increase in libido was noted in 37.3% of patients.

After treatment in patients with BPH stages I and II,uroflograms recorded the restoration of the basic parameters of urination to normal values. At stage III of the disease, this was prevented by a decrease in the elasticity of the bladder neck due to sclerotic changes in the tissue of the prostate gland. Still, a noticeable increase in the urine stream was observed in such patients.

Thus, the results of this study indicate the therapeutic efficacy of LIBIDON® and its use in the complex treatment of inflammatory diseases of the prostate and dysuric disorders.

LIBIDON® does not cause side effects, complications, or drug dependence and can be used for therapeutic and prophylactic purposes, including in combination with any means of symptomatic therapy used in urological practice (antibacterial agents, antispasmodics, vascular and hormonal drugs, vitamins, etc.)

CONCLUSION

Biologically active food supplement LIBIDON® has a normalizing effect on the functional activity of prostate cells.

LIBIDON® is well tolerated when taken orally, has no side effects, and can be used as a therapeutic and prophylactic biologically active food supplement.

LIBIDON® is recommended to patients with chronic prostatitis and prostatic hyperplasia orally with meals, 1-2 capsules 2 times a day for 30 days.

According to indications, a second course of treatment should be carried out after 3-6 months.

REFERENCES

1. Lyulko A.V., Yunda I.F., Sernyak P.S. and others.- Diseases of the prostate gland. - Kiev: Zdorov'ya, 1984. -- 280 p.

2. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO "Gamta", 1993.

3. Tkachuk V.N., Gorbachev A.G., Agulyansky L.I. Chronic prostatitis. - L .: Medicine, 1989 .-- 208 p.

RECOMMENDATIONS FOR USE

LIBIDON® is a complex of peptides obtained from the prostate gland of young animals. The isolated peptides have a selective effect on prostate cells, normalize metabolism in prostate cells, and regulate the functions of the reproductive system in men.
In a clinical study, the effectiveness of LIBIDON® in the complex treatment of patients with chronic prostatitis and prostatic hyperplasia, for the restoration of the functions of the reproductive system in men after diseases of various origins, under the influence of extreme environmental factors, malnutrition, as well as aging, has been established.
It is recommended to take LIBIDON® 1-2 capsules or tablets 1-2 times a day with meals. The duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.
Do not use in case of individual intolerance to the components.
Side effects when using LIBIDON® have not been identified.
It is recommended to store it in a dry, dark place at a temperature from +2 to +25 °C.
Release form: 20 capsules or tablets containing 10 mg of LIBIDON®.
Expiration date: 3 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Pielotax®

Report on the results of clinical studies of the biologically active food supplement **Pielotax®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement PIELOTAX® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from kidney tissues of young animals - calves up to 12 months of age or pigs.
PIELOTAX® is available in capsules with an active substance content of 10 mg.
PIELOTAX® peptides regulate metabolic processes in kidney tissue cells, increase the reserve capacity of the urinary system, have a beneficial effect on the body's adaptation processes in extreme conditions, and have antioxidant properties, regulating the processes of peroxidation in the kidneys.
Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This allows us to assume the effectiveness of PIELOTAX® for the restoration of kidney function in case of disorders of various origins.
Metabolic disorders, hypertension, infectious and autoimmune lesions, especially with age, often lead to kidney damage (3).
Drug treatment of kidney disease includes the use of the following drugs (1, 2):
- Drugs of the 4-aminoquinoline range - delagil, plaquenil;
- Immunomodulators - thymalin, levamisole;
- Antihypertensive drugs;
- Vitamins C and E (antioxidants);
- etc.

The clinical study of PIELOTAX® was carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology from February to August 2011.
Clinical trials of PIELOTAX® were carried out in patients with gouty nephropathy. A total of 42 patients took part in the study. The distribution of patients by sex and age is presented in Table 1. Patients with gouty nephropathy complained of recurrent pain in the joints. In connection with the prolonged course of the disease in a number of patients, the inflammatory changes carried obliterated traits.
All patients previously received symptomatic and pathogenetic therapy for the disease, which contributed to a temporary decrease in the severity of symptoms.
The patients were randomized into 2 groups - the control group (15 people) and the primary group (27 people). Patients in the control group received only conventional therapy.
In addition to conventional therapy, patients of the primary group received PIELOTAX® orally 10-15 minutes before meals, 1-2 capsules 3 times a day for 30 days, depending on the severity of the pathological process.

Distribution of patients by diagnosis, sex and age.

Table 1

Diagnosis	Age	Group	Male	Female	Total
Gouty nephropathy	43-67	Control	9	6	15
	42-68	Primary	19	8	27
Total:			28	14	42

RESEARCH METHODS

The patients' complaints were assessed in dynamics, a general clinical examination of blood and urine, a biochemical study of blood on the REFLOTRON apparatus (Boehringer Mannheim, Germany) were carried out. Ultrasound examination of the kidneys was performed using an ultrasound machine (ALOKA, Japan).

RESEARCH RESULTS

As a result of the studies, it was found that the use of PIELOTAX® helped to smooth the clinical manifestations of gouty nephropathy in 78% of cases. However, the most revealing was the data of laboratory research. While taking the drug, the activation of the metabolism of renal tissues was observed, accompanied by an increase in the secretory function of the kidneys, which is reflected in the dynamics of the biochemical parameters of the patients' blood (Table 2).

As can be seen from the data shown in Table 2, in the control group, after treating patients with conventional methods, an improvement in blood biochemical parameters, reflecting renal function, was observed. However, these indicators did not reach normal values. In patients of the primary group, blood biochemical parameters were close to normal values for men and women. Thus, the residual nitrogen in the control group was on average 35.4 ± 0.8 mmol/l before treatment, and after treatment - 30.5 ± 0.6 mmol/l ($p < 0.05$), however, in patients of the primary group, this indicator decreased to 27.1 ± 0.4 mmol/l, which is significantly lower compared to the indicator in the control group and corresponds to the lower limit of the norm (28.6 mmol/l). The same trend can be traced in the dynamics of the urea content in the blood: a decrease in the initially increased indicator is observed in patients of both groups. However, in the primary group, the indicator was 9.2 ± 0.3 mmol/l, which brings its normal value closer to its average value (8.3 mmol/l). Changes in the content of uric acid are also characteristic: in both men and women of the primary group, after further use of the study drug, the indicators returned to normal - in men, the content of uric acid decreased to 0.44 ± 0.02 mmol/l (in the control group, 0.56 ± 0.01 mmol/l, the norm is up to 0.50 mmol/l); in women of the primary group - up to 0.37 ± 0.03 mmol/l (in the control group 0.48 ± 0.02 mmol/l, the norm is up to 0.40 mmol/l).

Influence of PIELOTAX®on the biochemical parameters of the blood of patients with gouty nephropathy.

Table 2

Indicators	Before Treatment		After Treatment	
	Control Group	Primary Group	Control Group	Primary Group
Residual nitrogen, (mmol/l)	35,4±0,8	34,1±0,7	30,5±0,6*	27,1±0,4*#
Residual nitrogen, (mmol/l)	14,7±0,5	13,8±0,6	11,8±0,5*	9,2±0,3*#
Uric acid, (mmol/l) **- women** **- men**	 0,57±0,01 0,75±0,03	 0,55±0,02 0,78±0,04	 0,48±0,02* 0,56±0,01*	 0,37±0,03*# 0,44±0,02*#

* - $p < 0.05$ compared with the indicator in the same group before treatment.
# - $p < 0.05$ compared to the same indicator in the control group

Thus, the results obtained indicate the therapeutic effectiveness of PIELOTAX®and the advisability of its use in the complex treatment of patients with gouty nephropathy and other diseases associated with impaired renal function.

PIELOTAX®does not cause side effects, complications, or drug dependence.

PIELOTAX®can be used for therapeutic and prophylactic purposes in the form of a biologically active food supplement combined with any means of symptomatic and pathogenetic therapy used to treat patients with gouty nephropathy and other kidney diseases.

CONCLUSION

Biologically active food supplement PIELOTAX® has a normalizing effect on metabolism in kidney tissues.
PIELOTAX® is well tolerated when administered orally. It has no side effects and can be widely used as a therapeutic and prophylactic biologically active food supplement.
PIELOTAX® is recommended to patients with gouty nephropathy and other kidney diseases to be administered orally 10-15 minutes before meals, 1-2 capsules 2-3 times a day for 15-30 days, depending on the severity of the pathological process.
It is possible to repeat the course of treatment in 3-6 months.
It is advisable to recommend PIELOTAX® for therapeutic and prophylactic use and industrial production.

REFERENCES

1. Belousov Y.B., Moiseev V.S., Lepakhin V.K. Clinical Pharmacology and Pharmacotherapy: A Guide for Physicians. - M.: the Universe, 1993. -- 398 p.
2. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
3. Geriatric manual / Ed. D.F. Chebotarev, N.B. Mankovsky. – M.: Medicine, 1982. – 544 p.

RECOMMENDATIONS FOR USE

PIELOTAX®is a complex of peptides obtained from the kidneys of young animals. The isolated peptides have a selective effect on various cells of kidney tissues, normalize metabolism in cells, and regulate their functions.
In the clinical study, the effectiveness of PIELOTAX®has been established for the complex restoration of the functions of the urinary system after diseases of various origins, in pathological conditions leading to impaired renal function, exposure to extreme environmental factors, malnutrition, as well as aging.
Take 1-2 capsules or tablets of PIELOTAX®1-2 times a day with meals. The duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.
Do not use in case of: individual intolerance to the components, pregnancy, or breastfeeding.
No side effectshave been identified when using PIELOTAX®.
Store in a dry, dark place at a temperature from +2 to +25 °C.
Release form: 20 capsules or tablets containing 10 mg of PIELOTAX®.
Expiration date: 5 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Svetinorm®

Report on the results of clinical studies of the biologically active food supplement **Svetinorm®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement SVETINORM® is a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, obtained from the liver of young animals - calves not older than 12 months of age or pigs. The isolated peptides have a tissue-specific effect on liver cells, restoring metabolism and normalizing their functional activity.
SVETINORM® is available in tablets or capsules containing 10 mg of active peptides.
Clinical trials of SVETINORM® were carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS, in patients with chronic hepatitis and cancer after a course of radiation or radiation chemotherapy in the period from October 2005 to January 2006.
SVETINORM® was taken by patients orally 10-15 minutes before meals, 1-2 capsules 2 times a day for 10-20 days, depending on the severity of the pathological process.
Chronic hepatitis is considered not an outcome of an acute infectious process but as a form of the course of the infectious process (2, 3). Currently, there is an increase in the number of patients with chronic liver lesions, which are prevalent mainly in people of working age. Adverse social and environmental factors play a significant role in increased morbidity.
In the treatment of patients with chronic hepatitis, taking into account the pathogenetic mechanisms, mainly the following conventional means are used (1):
- Drugs that improve the exchange of liver cells (hepatoprotectors) - Essentiale, Legalon, Sirepar;
- Stimulants of bile secretion - Liv-52;
- Vitamins of group B (B1, B6, B12), ascorbic acid;
- etc.

CLINICAL CHARACTERISTICS OF PATIENTS

Clinical trials were carried out in 47 patients with chronic hepatitis and cancer after a course of chemotherapy, including 30 men and 17 women aged 35 to 68 years (Table 1). In addition to conventional treatments, patients of the primary group received Svetinorm® 2 capsules 2 times a day before meals for 15-20 days. The duration of the disease ranged from 3 to 10 years.
The control groups consisted of 38 similar patients prescribed only conventional drugs.

Distribution of patients by nosological forms, sex and age. Table 1

Diagnosis	Age	Male	Female	Total
Chronic persistent hepatitis	35-56	21	13	34
Condition after a course of chemotherapy in cancer patients	53-68	9	4	13
Total:		30	17	47

Most patients complained of pain in the right hypochondrium, general weakness, and rapid fatigability. In 73% of patients, dyspeptic disorders were noted. In 53% of patients, hyperbilirubinemia, an increase in the level of alanine aminotransferase, an increase in the globulin fraction of blood proteins, mainly due to the fraction of immunoglobulins M, were noted, which indicates a certain activity of the chronic inflammatory process.

RESEARCH METHODS

Patients' complaints were assessed subjectively in dynamics. A general clinical examination of blood and urine, biochemical and immunological blood tests (determination of immunoglobulins according to Mancini), and ultrasound examination of the liver were performed.

RESEARCH RESULTS

After treatment with SVETINORM®, most patients noted the disappearance of weakness, an increase in appetite and performance. In 53% of patients, the intensity of pain syndrome significantly decreased. Cancer patients noted an improvement in their well-being, a decrease in weakness, and decreased intensity of dyspeptic disorders

Influence of SVETINORM® on the biochemical parameters of peripheral blood of patients with chronic hepatitis.

Table 2

Indicator	Before Treatment	After Treatment with Conventional Means	After Treatment with Svetinorm®
Cholesterol, (mmol/l)	4,6±0,2	5,2±0,3	5,0±0,4
Bilirubin, (µmol/l)	27,1±1,2	23,6±1,4	20,1±0,8*
AST, (mmol /h•l)	41,0±2,5	39,1±2,7	38,8±2,6
ALT, (mmol/h•l)	52,5±4,1	46,1±3,8*	43,5±3,5*
y-HT, (mmol / h•l)	44,7±4,3	42,6±4,0	41,4±4,1
Triglycerides, (mmol/l)	2,3±0,1	2,1±0,4	1,7±0,6*

* P <0.05 - significant compared with the indicator before treatment.

When analyzing the effectiveness of SVETINORM®, particular attention was paid to assessing the results of the biochemical studies characterizing the aminotransferase activity, pigment, and protein-forming functions of the liver. Objectively, after the use of SVETINORM®, the stabilization of the biochemical parameters was observed in most patients: the level of bilirubin, alanine aminotransferase (Table 2). The study of peripheral blood immunoglobulins, an essential criterion for the inflammatory process activity, after a course of treatment with SVETINORM®, showed a decrease in IgM level (Table 3).

Influence of SVETINORM® on immunological parameters in patients with chronic hepatitis.

Table 3

Indicators	Before Treatment	After Treatment with Conventional Means	After Treatment with Svetinorm®
IgA, (g/l)	2,20±0,1	2,30±0,04	2,10±0,06
IgM, (g/l)	3,90±0,05	2,30±0,07*	1,60±0,04*
IgG, (g/l)	14,5±1,0	13,7±1,1	14,0±1,2

* P <0.05 - significant compared with the indicators before treatment.

RECOMMENDATIONS FOR USE

SVETINORM® is recommended to accelerate the recovery of liver function in acute or chronic liver damage, in the treatment of antibiotics and other drugs that adversely affect the liver, malnutrition, in cancer patients after radiation or chemotherapy, and when the body is exposed to various extreme factors. Also, it is recommended for the elderly to maintain liver function.
It is recommended to take SVETINORM® 10-15 minutes before meals, 1-2 tablets or capsules 2-3 times a day for 15-20 days.
It is advisable to repeat the course in 3 - 6 months.

REFERENCES

1. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
2. Podymova S.D. Liver diseases. – M.: Medicine, 1984. – 480 p.
3. Rakhmanova A.G., Prigozhina V.K., Neverov V.A. Infectious diseases: Manual for general practitioners. – M.-SPb.: Pub. “SSZ”, 1995. – 304 p.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Sigumir®

Report on the results of clinical studies of the biologically active food supplement **Sigumir®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement SIGUMIR® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the cartilage tissue of young animals - calves up to 12 months of age or pigs.
SIGUMIR® is available in tablets or capsules with an active ingredient content of 10 mg.
Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. They improve the trophism of cartilage cells and have a regulatory effect on its metabolic processes, reducing the risk of various lesions of the joints and spine. This suggests the effectiveness of the use of SIGUMIR® to restore the function of cartilage tissue in inflammatory and dystrophic-degenerative diseases of the musculoskeletal system.
Clinical trials of SIGUMIR® were carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology in patients with osteoarthritis of the joints, osteochondrosis of the spine, and osteoporosis in the period from November 2005 to February 2006.
SIGUMIR® was administered to patients orally 10-15 minutes before meals, 1-3 capsules 2-3 times a day for 30-45 days, depending on the severity of the pathological process.
The treatment and rehabilitation of patients with degenerative-dystrophic diseases of the joints and spine, occurring with irreversible, progressive manifestations, is a complex problem that is most urgent in geriatric practice (2, 3).
Drug therapy for degenerative-dystrophic diseases of the joints and spine includes the use of various drugs of symptomatic and pathogenetic action (1):
- Analgesics and anti-inflammatory drugs (analgin, novocaine blockade, rheopyrin, indomethacin, brufen);
- Antihistamines (diphenhydramine, pipolfen);
- Drugs that improve peripheral blood circulation (pachikarpin, platifillin);
- Biostimulants (rumalon, aloe, vitreous body, ATP);
- Enzyme medication (lidase, ronidase);
- Anabolic steroids (nerabol, retabolil);
- etc.

CLINICAL CHARACTERISTICS OF PATIENTS

Treatment with SIGUMIR® was carried out in 33 patients with diagnoses of osteoarthritis of the knee joints (10 people, including 7 men, 3 women), osteochondrosis of the spine (15 people, including 6 men, 9 women), osteoporosis (8 women). The patients' age ranged from 45 to 78 years.
The control group included 31 patients with similar diagnoses, gender, and age. The distribution of patients by diagnosis, sex, and age is shown in Table 1.
Osteoporotic patients complained of frequent bone fractures arising from minor trauma or even for no apparent reason.
The duration of the course of the disease ranged from 5 to 20 years. There were progressive dynamics of the development of the pathological process.
In patients of the primary and control groups, the duration of the disease ranged from 5 to 20 years, and there were progressive dynamics of the development of the pathological process.
All patients had previously received analgesics and anti-inflammatory drugs for a long time, the use of which caused a short-term therapeutic effect, requiring an increase in the dose of drugs for the course of treatment and their prolonged use.
Patients in the control group received treatment using conventional means. In addition to conventional means, patients of the primary group were prescribed SIGUMIR® 2-3 capsules 2-3 times a day before meals for 30-45 days.

Distribution of patients by diagnosis, sex and age. Table 1

Diagnosis	Age	Male		Female		Total	
		Control Group	Primary Group	Control Group	Primary Group	Control Group	Primary Group
Knee osteoarthritis	59-78	6	7	3	3	9	10
Osteochondritis of the spine	45-69	7	6	8	9	15	15
Osteoporosis	45-65	-	-	7	8	7	8
Total:		13	13	11	12	31	33

RESEARCH METHODS

To assess the effectiveness of the use of SIGUMIR®, we analyzed the dynamics of patients' complaints and objective indicators: general clinical examination of blood and urine, biochemical blood test, and X-ray.

RESEARCH RESULTS

It should be noted that the radiology symptoms of degenerative-dystrophic diseases of the joints and the spine are not only objective diagnostic criteria for the stage of development of the pathological process but also have a great prognostic value in drug therapy.

It was found that the use of SIGUMIR® in patients with osteoarthritis of the knee joints contributed to a decrease in pain syndrome and an increase in joint mobility in 68.5% of cases. At the same time, pain symptoms disappeared almost entirely at the radiologically determined initial stages of the disease: narrowing of the joint space between the patella and the thigh, lateral osteophytes of the patella, and femoral condyle. No significant dynamics of radiological symptoms were observed during this period.

In patients in the advanced stage of arthrosis, a similar but less pronounced dynamics of subjective indicators was observed. Since this stage of the disease was diagnosed in persons of the older age group, such subjective sensations were characterized as very favorable.

In patients with osteochondrosis of the lumbar spine, the use of SIGUMIR® against the background of complex therapy helped reduce pain in 53.7% of cases. A progressive course of the disease with age, accompanied by characteristic X-ray symptoms (narrowing of the lumen between adjacent vertebral bodies due to flattening of degeneratively altered intervertebral discs; the formation of anterior and posterior osteophytes of the vertebral bodies, the presence of arthritic changes in the posterior and lateral intervertebral joints in the form of narrowing of the crevices, unevenness development of osteophytes along the edges of the articular ends; changes in the configuration of the intervertebral foramen), contributed to the development of spondylosis and spondyloarthrosis and the formation of neurodystrophic and neurovascular syndromes. These dynamics were most typical for middle-aged people. In these cases, long-term (at least 45-60 days) use of SIGUMIR® smoothed out pain symptoms arising from stress on the spine and lower extremities and increased the spine's mobility.

In patients with osteoporosis, with prolonged use of the drug, the stabilization of metabolic processes in the bone tissue was noted: the number of characteristic fractures decreased, the process of restoration of the function of the musculoskeletal system was significantly accelerated, and the time spent in the hospital decreased.

All patients showed a significant smoothing of the main symptoms of this group of diseases, characterized by substantial conservatism.

SIGUMIR® does not cause side effects, complications, or drug dependence.
Thus, the results of this study indicate the therapeutic efficacy of SIGUMIR® and the practicality of its use in the complex treatment and prevention of degenerative-dystrophic diseases of the joints and spine in combination with any means of symptomatic and pathogenetic therapy used to treat this group of diseases (analgesics, anti-inflammatory, antihistamines, and vascular agents, biostimulants, enzyme preparations, anabolic steroids, vitamins, etc.).

CONCLUSION

The biologically active food additive SIGUMIR® promotes the normalization of metabolic processes in the cartilaginous tissue and slows down its involutive changes.
SIGUMIR® can be used for therapeutic and prophylactic purposes as a biologically active food supplement combined with any means of symptomatic and pathogenetic therapy used to treat degenerative-dystrophic diseases of the joints and spine - osteoarthritis, osteochondrosis, osteoporosis, etc.

REFERENCES

1. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
2. V.A. Nasonova, M.G. Astapenko Clinical Rheumatology: A Guide for Physicians. - M.: Medicine, 1989. -- 592 p.
3. Geriatric manual / Ed. D.F. Chebotarev, N.B. Mankovsky. – M.: Medicine, 1982. – 544 p.

RECOMMENDATIONS FOR USE

A complex of peptides isolated from cartilage and bone tissues. The isolated peptides have a selective effect on various cells of cartilage and bone tissues, normalize cell metabolism, and regulate the functions of the joints and spine.
In a clinical study, the effectiveness of Sigumir® was established for the complex restoration of the functions of the musculoskeletal system after suffering diseases of various origins in pathological conditions leading to dysfunction of cartilage and bone tissues, exposure to extreme environmental factors, malnutrition, and also during aging.

SIGUMIR® is well tolerated by patients when taken orally, has no side effects, and can be widely used as a therapeutic and prophylactic biologically active food supplement.
SIGUMIR® is recommended:
- To patients with osteoarthritis of the joints - orally 10-15 minutes before meals, 2 tablets or capsules 3 times a day for 45 days;
- To patients with osteochondrosis of the spine - orally 10-15 minutes before meals, 2 tablets or capsules 3 times a day for 45 days;
- To patients with osteoporosis - orally 2 tablets or capsules 2 times a day 10-15 minutes before meals for 30 days.
It is recommended to repeat the course of treatment in 3-6 months.
It is advisable to recommend SIGUMIR® for therapeutic and prophylactic use and industrial production.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Stamakort®

Report on the results of clinical studies of the biologically active food supplement **Stamakort®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement STAMAKORT® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the gastric mucosa tissues of young animals - calves up to 12 months of age or pigs.
STAMAKORT® is available in capsules with an active substance content of 10 mg.
STAMAKORT® peptides regulate metabolic processes in the gastric mucosa cells, increase the reserve capacity of the gastrointestinal tract, have a beneficial effect on the adaptation processes of the body in extreme conditions, have antioxidant properties, and regulate the processes of peroxidation in the tissues of the gastric mucosa. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This allows us to assume the effectiveness of the use of STAMAKORT® to restore the functions of the gastrointestinal tract with disorders of various origins.
Chronic inflammatory diseases of the stomach and duodenum and postoperative complications are the cause of the formation of functional insufficiency and disorders of the secretory and motor functions of various parts of the gastrointestinal tract (1, 2, 3), which significantly reduce the quality of life of people of different ages.
Medical treatment of these diseases includes the use of the following drugs (2, 3):
- Enzyme drugs that improve digestion (pepsin, panzinorm, mezim-forte, festal);
- Bitters (centaury grass, wormwood herb, dandelion root);
- Ganglion blockers (hexonium, metacin);
- Multivitamins;
- Biostimulants (aloe);
- etc.

The clinical study of STAMAKORT® was carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology from February to August 2011.
In clinical trials of STAMAKORT®, 47 patients with chronic gastritis took part, who complained of a feeling of heaviness and fullness in the epigastric region, bloating, belching with food or air, rumbling in the abdominal cavity, stool disturbance, and general weakness. At times the patients were disturbed by a dull, aching pain in the epigastric region after eating. The distribution of patients by sex and age is shown in Table 1.
All patients previously received symptomatic and pathogenetic therapy for these diseases.
The patients were randomized into 2 groups. The control group included 17 patients who received conventional therapy.
In addition to conventional therapy, patients of the primary group (30 people) received STAMAKORT® orally 10-15 minutes before meals, 1-2 capsules 3 times a day for 30 days, depending on the severity of the pathological process.

Distribution of patients by sex and age. Table 1

Diagnosis	Age	Group	Male	Female	Total
Chronic gastritis with secretory insufficiency	36-72	Control	10	7	17
	35-70	Primary	19	11	30
Total:			29	18	47

RESEARCH METHODS

The patients' complaints were assessed in dynamics, a general clinical examination of blood and urine, and a biochemical study of blood on the REFLOTRON apparatus (Boehringer Mannheim, Germany) were carried out. Determination of the secretory function of the stomach and fibrogastroscopywere carried out as well.

RESEARCH RESULTS

As a result of the studies, it was found that the use of STAMAKORT® helped to smooth the clinical manifestations of chronic gastritis in 86% of cases, and the most significant effect was observed in persons of the older age group, in whom signs of atrophic changes in the gastric mucosa were noted during the fibrogastroscopy.

The laboratory examination of gastric juice showed insufficiency of the secretory function of the stomach in the examined patients of both groups before treatment (Table 2).

The indices of total acidity and free hydrochloric acid in patients of both groups were at the lower limit of the norm before treatment, which was clinically manifested by symptoms of hypoacidity. After treatment with conventional means in patients of the control group, the indicators of total acidity and free hydrochloric acid increased, respectively, from 24.2 ± 2.1 mmol/l to 31.4 ± 2.4 mmol/l, and in patients of the primary group - up to 37, 1 ± 1.8 mmol/l, which is significantly higher than in the control group ($p < 0.05$). The same trend was observed when studying the dynamics of changes in the indicator of the content of free hydrochloric acid. As a result of the action of STAMAKORT®, there was an optimization of indices of gastric secretory function in patients of the primary group since the index of total acidity, and the content of free hydrochloric acid approached normal values.

Influence of STAMAKORT®on gastric secretory function in patients with chronic gastritis.

Table 2

Indicators	Before Treatment		After Treatment	
	Control Group	Primary Group	Control Group	Primary Group
Total acidity on an empty stomach, (mmol/l)	24,2±2,1	22,6±1,7	31,4±2,4*	37,1±1,8*#
Free HCl, (mmol/l)	11,3±1,1	14,3±1,7	15,9±1,3*	19,2±1,5*
HCl flow rate, (mmol/h)	1,21±0,08	1,13±0,01	1,57±0,05	1,86±0,03
Free HCl flow rate, (mmol/h)	0,56±0,03	0,72±0,04	0,79±0,07	0,96±0,04

* - $p < 0.05$ compared with the indicator in the same group before treatment.
# - $p < 0.05$ compared to the same indicator in the control group.

When examining the contents of the gastric juice in patients of the primary group in the process of taking STAMAKORT®, there was an increase in gastric acidity, a decrease in inflammatory changes in the gastric mucosa, and a reduction in mucus and food debris in the test portions taken on an empty stomach, which indicate an increase in the secretory and evacuation functions of the stomach.

Clinical patients noted a decrease in the manifestations of dyspeptic disorders, a decrease in pain syndrome, and improved well-being.

The normalization of digestion in patients with chronic disease is associated with the regulatory effect of STAMAKORT®, not only on the function of the gastric and duodenal mucosa cells but also by stimulating the enzymatic activity of the duodenal contents.

Thus, the results obtained indicate the effectiveness of STAMAKORT® and the advisability of its use in the complex treatment of chronic gastritis.

STAMAKORT® does not cause side effects, complications, or drug dependence.

STAMAKORT® can be used for therapeutic and prophylactic purposes in the form of a biologically active food supplement and in combination with any means of symptomatic and pathogenetic therapy used to treat chronic gastritis.

CONCLUSION

Biologically active food additive STAMAKORT®has a normalizing effect on metabolism in the gastric mucosa tissues.

STAMAKORT® is well tolerated when taken orally, has no side effects, and can be widely used as a therapeutic and prophylactic biologically active food supplement.
STAMAKORT® is recommended for oral administration in patients with chronic gastritis 10-15 minutes before meals, 1-2 capsules 2-3 times a day for 15-30 days, depending on the severity of the pathological process.
It is recommended to carry out repeated courses of treatment in 3-6 months.

REFERENCES

1. Belousov Y.B., Moiseev V.S., Lepakhin V.K. Clinical Pharmacology and Pharmacotherapy: A Guide for Physicians. - M.: the Universe, 1993. -- 398 p.
2. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO "Gamta", 1993.
3. Geriatric manual / Ed. D.F. Chebotarev, N.B. Mankovsky. – M.: Medicine, 1982. – 544 p.

RECOMMENDATIONS FOR USE

STAMAKORT®is a complex of peptides obtained from the gastric mucosa of young animals. The isolated peptides have a selective effect on various cells of the gastric mucosa tissues, normalize metabolism in the corresponding cells, and regulate their functions.
In the clinical study, the effectiveness of STAMAKORT®for the complex restoration of the functions of the digestive system after diseases of various origins, in pathological conditions leading to dysfunction of the stomach, exposure to extreme environmental factors, malnutrition, as well as aging, has been established.
Take 1-2 capsules or tablets of STAMAKORT®1-2 times a day with meals. The duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.
Do not use in case of: individual intolerance to the components, pregnancy, or breastfeeding.
No side effects when using STAMAKORT®have been identified.
Store in a dry, dark place at a temperature from +2 to +25 °C.
Release form: 20 capsules or tablets containing 10 mg of STAMAKORT®.
Expiration date: 5 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Suprefort®

Report on the results of clinical studies of the biologically active food supplement **Suprefort®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement SUPREFORT® is a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, obtained from the pancreas of young animals - calves not older than 12 months of age or pigs. The isolated peptides have a tissue-specific effect on the pancreas cells, restoring metabolism and normalizing their functional activity.
SUPREFORT® is available in tablets or capsules containing 10 mg of active peptides.
SUPREFORT® was administered to patients orally 10-15 minutes before meals, 1-2 capsules 2 times a day for 10-20 days, depending on the severity of the pathological process.
Clinical trials of SUPREFORT® were carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS in patients with chronic pancreatitis in remission and patients with type II diabetes mellitus in the period from November 2005 to January 2006.
Dysregulation of physiological functions and pathological changes in the pancreas causes diseases with digestive and metabolic disorders manifestations.
The consequence of a progressive inflammatory process in the pancreas is, as a rule, dystrophic processes, accompanied by a violation of the formation and secretion of pancreatic digestive enzymes, characteristic of chronic pancreatitis. In the presence of disorders of insulin secretion, the symptoms of «secondary» diabetes develop.
Diabetes is one of the most common endocrine diseases: it affects about 1-2% of the world's population. In addition, there is almost the same number of patients with latent diabetes and genetically predisposed to this disease. The manifestations of diabetes in each case represent an integrated reaction to the combined action of numerous factors in different combinations (genetic predisposition, chemical and infectious agents of the external environment, autoimmune processes, nutrition, physical activity, psychological stress, etc.). The discovery of new syndromes (diabetes caused by the formation of antibodies to insulin receptors; diabetes caused by a genetic defect in the structure of insulin, etc.) justifies the constant need to supplement the existing classifications of the disease. The disease's potential latent and asymptomatic forms, occurring without clinical manifestations, draw particular attention to prognosis, prevention, and treatment (1, 3, 6, 7, 8).
For the treatment of chronic pancreatitis, diet therapy and enzyme preparations (pancreatin, panzinorm), and others are mainly used (5)
Treatment of diabetes without clinical manifestations includes diet therapy and herbal medicine (2, 4).

CLINICAL CHARACTERISTICS OF PATIENTS

The distribution of patients who took part in the study by sex and age is presented in Table 1. Treatment with SUPREFORT® was carried out in 34 patients (18 men and 16 women) with diagnoses of «Chronic pancreatitis,» latent form (12 people), and «Diabetes mellitus type II, latent form» (22 people). Patients with chronic pancreatitis complained of loss of appetite, belching, flatulence, rumbling in the abdomen, and stool disorders. By random distribution, two groups of patients were formed, equal in sex, age, diagnosis: the primary group included 12 patients (8 men, 4 women), the control group - 8 patients (4 men, 4 women).

Distribution of patients by diagnosis, sex and age.

Table 1

Diagnosis	Age	Male		Female		Total	
		Control Group	Primary Group	Control Group	Primary Group	Control Group	Primary Group
Chronic pancreatitis	39-68	4	8	4	4	8	12
Type II diabetes mellitus	42-64	6	10	11	12	17	22
Total:		10	18	15	16	25	34

Patients in the control group received conventional treatment. In addition to conventional drugs, patients of the primary group were prescribed SUPREFORT® 1-2 capsules 2 times a day before meals for 15 days.

Diabetes mellitus type II occurred in patients without any clinical manifestations and was diagnosed based on an increase in glucose level in the peripheral blood, taking into account an unbalanced diet. The control group consisted of 17 patients prescribed medication using conventional treatment. 22 patients included in the primary group, in addition to traditional therapy, including antihyperglycemic agents, received 1 capsule of SUPREFORT® 2 times a day before meals for 15 days.

RESEARCH METHODS

The patients' complaints were assessed in dynamics, a general clinical examination of blood and urine, and a biochemical study of blood on the REFLOTRON apparatus (Boehringer Mannheim, Germany) were carried out. The duodenal contents were examined. A glucose tolerance test was performed.

RESEARCH RESULTS

It was found that the use of SUPREFORT® in patients with chronic pancreatitis promoted an increase in appetite and a decrease in the frequency of dyspeptic disorders.

Influence of SUPREFORT® on the activity of digestive enzymes in patients with chronic pancreatitis.

Table 2

Indicator	Before Treatment	After Treatment with Conventional Means	After Treatment with Suprefort®
Trypsin, (mmol/l)	2,14±0,09	2,72±0,12	2,9±0,1
α-amylase, kg / (h●l)	5,2±0,4	5,7±0,3	6,1±0,4

In a laboratory study of the duodenal contents, an initial decrease in the activity of pancreatic enzymes was noted (Table 2). As a result of the use of SUPREFORT®, there was a tendency to an increase in the activity of pancreatic enzymes, which correlated with an improvement in clinical symptoms.
In patients with type II diabetes mellitus, SUPREFORT® was used under the control of a glucose tolerance test. After the sugar load, it was found that the patients had a characteristic glycemic curve. In addition to the conventional treatment, patients of the primary group were prescribed SUPREFORT® 1 capsule 2 times a day before meals for 10 days. It was shown that after the use of SUPREFORT®, when the test was performed in the second hour of the study, a gradual decrease in blood glucose levels was observed. Normalization of blood glucose levels was achieved in all patients 5-10 days after starting the drug. None of the patients received an increase in the dosage of antihyperglycemic drugs, 12 patients (54.5%) had a reduced dose of conventional medications, and in 7 patients (31.8%), the blood glucose level did not exceed normal values without the use of antidiabetic drugs. The indicators remained at the initial level in 3 patients (13.6%). It should be noted that the indicator of glucose in the blood of patients of the primary group stabilized during the next 2-3 months after the end of the course of treatment (Table 3).

Influence of SUPREFORT® on blood glucose after carbohydrate load in patients with type II diabetes mellitus.

Table 3

Blood glucose (mmol/l)	Control Group		Primary Group	
	Before Treatment	After Treatment with Conventional Methods	Before Treatment	After Treatment with Suprefort®
On an empty stomach	8,2±0,9	6,6±0,4*	7,9±1,1	5,8±0,3*
2 hours after glucose intake	12,7±0,4	9,4±0,5	11,6±0,3	7,0±0,8* **

* P <0.05 - significant compared with the indicator before treatment;
** P <0.05 - significant compared with the indicator in patients of the control group.

CONCLUSION

Biologically active food supplement SUPREFORT® has a normalizing effect on the functional activity of pancreatic cells.
SUPREFORT® is well tolerated when administered orally, has no side effects, and can be used as a therapeutic and prophylactic biologically active food supplement in the complex treatment of pancreatic dysfunction.
- To patients with chronic pancreatitis - orally 10-15 minutes before meals, 1-2 tablets or capsules 2 times a day for 15 days;
- To patients with diabetes mellitus - orally 10-15 minutes before meals, 1 tablet or capsule 2 times a day for 15 days under the control of blood glucose.
It is advisable to repeat the course of treatment in 3-6 months

REFERENCES

1. Balabolkin M.I. Diabetes Mellitus / Endocrine Diseases / / Diagnosis and Treatment of Internal Diseases: A Guide for Physicians. Ed. F.I. Komarova. - M.: Medicine, 1991. - T. 2. - S. 465-492.
2. Belousov Y.B., Moiseev V.S., Lepakhin V.K. Clinical Pharmacology and Pharmacotherapy: A Guide for Physicians. - M.: the Universe, 1993. -- 398 p.
3. Internal Diseases / Ed. A.S. Smetnev, V.G. Kukes. - M.: Medicine, 1982. -- 496 p.
4. Yordanov D., Nikolov P., Boychinov Asp. Phytotherapy. - Sofia: Medicine and Physical Education, 1972. -- 346 p.
5. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
6. Geriatric manual / Ed. D.F. Chebotarev, N.B. Mankovsky. – M.: Medicine, 1982. – 544 p.
7. Tepperman J., Tepperman H. Physiology of metabolism and the endocrine system: Translation from English - M. Mir, 1989. -- 656 p.

RECOMMENDATIONS FOR USE

A complex of peptides isolated from the pancreas. The isolated peptides have a selective effect on various cells of the pancreas, normalize metabolism in cells, and regulate the functions of the pancreas.
In a clinical study, the effectiveness of SUPREFORT® was established for the complex restoration of pancreatic functions after past pancreatic diseases of various origins, in pathological conditions leading to pancreatic dysfunction, exposure to extreme environmental factors, impaired carbohydrate metabolism, malnutrition, and also during aging.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Taxorest®

Report on the results of clinical studies of the biologically active food supplement **Taxorest®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement TAXOREST® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the tissues of the bronchial mucosa of young animals - calves not older than 12 months of age or pigs.
TAXOREST® is available in capsules with an active substance content of 10 mg.
TAXOREST®'s peptides regulate metabolic processes in the bronchial mucosa cells, increase their reserve capacity, have a beneficial effect on the adaptation processes of the body in extreme conditions, have antioxidant properties, and regulate the processes of peroxidation in the tissues of the bronchial mucosa. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This allows us to assume the effectiveness of the use of TAXOREST® to restore the functions of the respiratory system in case of disorders of various origins, including a decrease in the reserve capacity of the bronchi when aging.
Chronic bronchitis is a severe medical and social problem due to the high prevalence, growing incidence, and substantial economic damage to society. Chronic bronchitis is the main form in the structure of chronic nonspecific lung diseases (3, 4).
Medical treatment of chronic bronchitis includes the use of the following drugs (1, 2):
- Antibiotics (penicillin, kanamycin, oleandomycin);
- Sulfa drugs (biseptol, madribone);
- Bronchodilators (aminophylline, ephedrine, salbutamol, phentolamine);
- Expectorants (bromhexine, thermopsis);
- Immunomodulators (thymalin, taktivin);
- Glucocorticoids (hydrocortisone, prednisolone, dexamethasone), etc.

CLINICAL CHARACTERISTICS OF PATIENTS

A clinical study of the effectiveness of TAXOREST® was carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology in the period from April to November 2011.
The study involved 52 patients aged 35 to 73 years, including 35 men and 17 women, with a diagnosis of chronic bronchitis and remission phase, divided into 2 groups. In addition to the conventional treatment, patients of the primary group received TAXOREST® 1 capsule 2 times a day with meals for 30 days.
The control group included 21 people comparable in diagnosis, sex, and age with the patients of the primary group. Patients in the control group received only conventional therapy.
Patients in both groups complained of coughing up phlegm, mainly in the morning, general weakness, sweating, shortness of breath during physical exercises, recurrent attacks of suffocation, sleep disturbances, and headaches. All examined patients had severe smoking habits.

RESEARCH METHODS

General clinical examination of blood and urine, biochemical blood study using the REFLOTRON apparatus (Boehringer Mannheim, Germany) were carried out. Also, radiography of the lungs, microscopic examination of sputum, and analysis of the function of external respiration were performed. Patients' complaints were assessed in dynamics.

RESEARCH RESULTS

It was found that the use of TAXOREST® in addition to conventional therapy in patients with chronic bronchitis in 82% of cases contributed to an improvement in well-being, a decrease in the frequency of coughing attacks, asthma attacks, and a decrease in the amount of sputum secreted. Positive dynamics of subjective indicators in the control group were observed in 57% of patients.
Auscultation of the lungs in dynamics showed a decrease in dry and buzzing wheezing.
During the use of TAXOREST®, a decrease in the microscopic structures of sputum was observed: leukocytes, epithelial cells, Kurshman's coils, which indicates a decrease in the inflammatory and bronchospastic manifestations of the disease.

The study of the function of external respiration showed that against the background of treatment with TAXOREST®, the indices of bronchial patency improved (Table 1).

The influence of TAXOREST® on the indicators of external respiration in patients with chronic bronchitis.

Table 1

Indicator	Before Treatment	After Treatment with Conventional Methods	After Treatment with Taxorest®
Lung vital capacity (VC), ml	3654,1 ±231,9	3876,5±215,4	4220,7 ±243,1*
Total lung capacity (TLC), ml	4730,2±276,5	5075,4±211,6	5246,1±223,6
Expiratory forced vital capacity of the lungs (EFVCL), ml	2767,8±134,7	3225,6±148,2	3940,5±123,6*

* - p <0.05 compared to the indicator before treatment.

The results of the study of the function of external respiration indicate a sufficiently compensated pathological process in the lungs, but, at the same time, there are phenomena of impaired bronchial patency, mainly due to spasm of small bronchioles. The use of TAXOREST® had a positive impact on the dynamics of the development of this process.
Thus, the results of this study indicate the therapeutic efficacy of TAXOREST® and the practicality of its use in the complex treatment of chronic bronchitis, including the bronchitis of smokers.
In the process of using TAXOREST®, no side effects, complications, contraindications, or drug dependence were identified.
TAXOREST® can be used for therapeutic and prophylactic purposes in the form of a biologically active food supplement and in combination with any means of symptomatic and pathogenetic therapy used to treat chronic bronchitis.

CONCLUSION

Biologically active food additive TAXOREST® has a normalizing effect on the functional activity of the bronchial mucosa cells.
TAXOREST® is well tolerated when taken orally, has no side effects, and can be used as a therapeutic and prophylactic biologically active food supplement.

REFERENCES

1. Belousov Y.B., Moiseev V.S., Lepakhin V.K. Clinical Pharmacology and Pharmacotherapy: A Guide for Physicians. - M.: the Universe, 1993. -- 398 p.
2. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
3. Paleev N.R., Tsarkova L.N., Borokhov A.I. Chronic nonspecific lung diseases. - M.: Medicine, 1985. -- 240 p.
4. Tsarkova L.N., Ilchenko V.A. Chronic nonspecific lung diseases / Diagnostics and treatment of internal diseases: A guide for doctors. Ed. F.I. Komarova. - M.: Medicine, 1991. - T. 2. - S. 106-250.

RECOMMENDATIONS FOR USE

TAXOREST® is a complex of peptides obtained from the bronchial mucosa of young animals. The isolated peptides have a selective effect on the bronchial mucosa cells, normalize their metabolism, and regulate the functions of the respiratory system.

A clinical study established the effectiveness of TAXOREST® in the complex treatment of patients with chronic bronchitis of various origins to restore the functions of the respiratory system after diseases of multiple origins, under the influence of extreme environmental factors, malnutrition, as well as aging.

Instructions for TAXOREST®: take 1-2 capsules or tablets 1-2 times a day with meals. The duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.

Do not use in case of:individual intolerance to the components, pregnancy, breastfeeding.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Testoluten®

Report on the results of clinical studies of the biologically active food supplement **Testoluten®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Testoluten®

The biologically active food supplement TESTOLUTEN® contains a complex of low molecular weight peptides with a molecular weight of up to 5,000 Da, isolated from the tissues of the testes of young animals - mature bulls.
TESTOLUTEN® is available in capsules with an active substance content of 10 mg.
TESTOLUTEN® peptides regulate metabolic processes in testicular cells, increase the reserve capacity of the male reproductive system, have a beneficial effect on the adaptation processes of the body in extreme conditions, and have antioxidant properties, regulating the processes of peroxidation in testis tissues. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This allows us to assume the effectiveness of the use of TESTOLUTEN® to restore the functions of the male reproductive system in case of its malfunctions of various origins.
The climax is a transitional period of qualitative restructuring of the body in new age-related conditions of the dynamic interaction of organs and systems to maintain the relative stability of homeostasis. Essentially it is a physiological syndrome caused by age-related shifts in hormonal and general metabolism and, above all, age-related extinction of the function of the gonads. In men, it occurs later than in women. It proceeds less noticeably and merges with the signs of old age. Symptoms of the male physiological climax can be observed in different age groups and varying degrees of severity. Changes in the functional state of the male reproductive glands play an important role for the male body in this period. It is generally accepted that involutionary processes primarily affect the endocrine function of the testicles.
The onset of atrophic processes in the interstitial tissue of the testicles with the involvement of glandulocytes in the process can be detected already at the age of 30-40 years. At the age of 50-60 years and older, the concentration of luteinizing hormone (LH), follicle-stimulating hormone (FSH), testosterone, and estradiol ratios change significantly. Changes in the hormonal background and the associated restructuring of the mental and neurohumoral components of the copulatory cycle underlie the extinction of the copulative function, which is manifested by a decrease in the frequency of sexual intercourse, a reduction in libido, and weakening of erections. In this case, the increase in pathological symptoms from the nervous, vascular and reproductive systems in men of the older age group are accompanied by pathological male climax (2, 3). Medical treatment of the climax is necessary only for those men in whom its manifestations significantly go beyond the physiological framework, leading to a disorder of critical functional systems of the body. In such cases, treatment should be comprehensive and include etiological, pathogenetic, and symptomatic components (1, 2, 3).
For the treatment of male climax, the following drugs are used:
- Hormonal drugs (methyltestosterone, testosterone propionate, sustanon-250, ambosex);
- Adaptogens (ginseng, extracts of Eleutherococcus, Leuzea, Rhodiolarosea, tinctures of aralia, zamanihi, saparal, pantocrine);
- Tranquilizers (elenium, seduxen, phenazepam, meprobamate, trioxazine);
- Antidepressants (clomipramine, melipramine);
- Vitamin therapy (vitamins B1, B6, B12);
- etc.

A clinical study of the effectiveness of TESTOLUTEN® was carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology in the period from May to November 2011.
The clinical study involved 36 men aged 47 to 65 years with a diagnosis of male climax.
Patients complained of rapid fatigue, decreased physical and mental performance, weakened memory, emotional instability, increased sweating, irritability, and surges in blood pressure. Still, most men paid particular attention to the appearance of sexual weakness.
Most of the patients did not previously seek medical help and independently took various medications that help to level pathological reactions.
The patients were divided into 2 groups (Table 1). Patients in the control group (14 people) received conventional therapy, excluding hormonal drugs.

In addition to conventional therapy, patients in the primary group (22 people) received TESTOLUTEN® 1 capsule 2 times a day with meals for 30 days.

Distribution of patients by groups.

Table 1

Diagnosis	Control Group		Primary Group	
	Age	Number of Patients	Age	Number of Patients
Male Climax	47-64	14	49-65	22

RESEARCH METHODS

Patients' complaints were assessed in dynamics, and general clinical examination of blood and urine, biochemical blood study using the REFLOTRON apparatus (Boehringer Mannheim, Germany) were carried out. Using a radioimmunological method, the content of sex hormones in the blood serum was determined. The radioactivity of the samples was counted on the «Tracor Analytic 1285» counter (USA-Holland). In addition, palpation of the prostate gland, laboratory examinations of secretion and ejaculation were performed.

RESEARCH RESULTS

The studies showed that in the examined patients, the manifestations of male climax result from predominantly hormonal changes in the body, characteristic of this age group. The severity of these manifestations in younger people is also due to various unfavorable environmental and occupational factors. An increase in blood glucose was noted in some patients, which probably indicates a "breakdown" of the insulin regulation system.

Changes in the concentration of sex hormones in the blood were characteristic (Table 2).

In almost all patients, genetic changes in the prostate gland were determined by palpation.

The use of TESTOLUTEN® against the background of complex treatment helped improve the general well-being of patients and increase libido.

It is imperative to note that TESTOLUTEN® had a regulatory effect on the content of sex hormones in the blood (Table 2). As can be seen from the data in Table 2, before treatment, the ratio of sex hormones was disrupted in all patients, while the content of all hormones, including testosterone, was at the lower limit of the norm. The use of TESTOLUTEN® led to a significant increase in the content of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) compared with the indicators both before treatment and in patients in the control group who received conventional therapy without hormonal drugs.

It is important to note that as a result of the use of TESTOLUTEN®, the testosterone content in the blood of patients of the primary group significantly increased compared to the indicator before treatment. No significant increase in testosterone content was observed in the patient's blood in the control group.

Effect of TESTOLUTEN®on the content of sex hormones in the peripheral bloodin patients with male climax.

Table 2

Indicator	Norm	Before Treatment	After Treatment with Conventional Methods	After Treatment with Testoluten®
LH, mU/ml	4,0-11,0	3,12±0,07	3,88±0,05*	4,65±0,07**
FSH, mU/ml	1,5-7,0	1,67±0,05	2,15±0,05*	2,96±0,09**
Testosterone, mU/ml	2,0-10,0	3,2±0,2	3,5±0,4	5,4±0,12*, **

* - p <0.05 compared with the indicator before treatment;
** - p <0.05 compared with the indicator in the control group.

As can be seen from the data in Table 2, the content of LH, FSH, and testosterone in the blood serum of patients in the control group increased compared to the indicators before treatment; however, it remained at the lower limit of the norm. In patients of the primary group, the testosterone content increased to normal values - 5.4 ± 0.12 ng/ml, which correlated with a significant improvement in well-being and the leveling of psychophysiological disorders - emotional instability, irritability, memory impairment, decreased physical and mental performance, as well as vegetative violations - increased sweating, headaches, and surges in blood pressure.
All patients of the primary group who took TESTOLUTEN® noted an increase in libido.
Microscopic examination of the ejaculate was indicative. There was an increase in the number of sperm and their mobility, a decrease in the pathological forms of sperm, and a decrease in the number ofleukocytes.
Thus, the results of this study indicate the therapeutic efficacy of TESTOLUTEN®and the advisability of its use in the complex treatment of male climax.
When using TESTOLUTEN®, no side effects were detected, no complications and drug dependence were registered.
TESTOLUTEN®can be used for therapeutic and prophylactic purposes in the form of a biologically active food supplement combined with any means of etiological, symptomatic, and pathogenetic therapy used to treat male climax.

CONCLUSION

The biologically active food additive TESTOLUTEN® has a regulating effect on the functional activity of testis cells and helps to normalize reproductive function in men.
TESTOLUTEN® is well tolerated when taken orally, has no side effects, and can be used as a therapeutic and prophylactic biologically active food supplement.
TESTOLUTEN® is recommended for use: to patients with male climax - orally 10-15 minutes before meals, 1 capsule 2 times a day for 30 days.
According to indications, a second course of treatment should be carried out after 3-6 months.
It is advisable to recommend TESTOLUTEN® for therapeutic and prophylactic use and industrial production.

REFERENCES

1. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
2. Guide to Andrology / Ed. O. L. Tiktinsky. - L.: Medicine, 1990. -- 416 p.
3. Sexopathology: A Handbook / Ed. G.S. Vasilchenko. - M.: Medicine, 1990. -- 576 p

RECOMMENDATIONS FOR USE

TESTOLUTEN® is a complex of peptides obtained from the testes of young animals. The isolated peptides have a selective effect on testicular cells, normalize cell metabolism, and regulate the functions of the reproductive system in men.
In the clinical study, the effectiveness of TESTOLUTEN® was established for the complex restoration of the functions of the reproductive system in men after diseases of various origins, in pathological conditions leading to impaired reproductive function in men, exposure to extreme environmental factors, malnutrition, as well as aging.

It is recommended to take TESTOLUTEN® 1-2 capsules or tablets 1-2 times a day with meals. The duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.
Do not use in case of individual intolerance to the components.
No side effects have been identified when using TESTOLUTEN®.
Store in a dry, dark place at a temperature from +2 to +25 °C.
Release form: 20 capsules or tablets containing 10 mg of TESTOLUTEN®.
Expiration date: 3 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Thyreogen®

Report on the results of clinical studies of the biologically active food supplement **Thyreogen®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

The biologically active food supplement THYREOGEN® is a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, obtained from the thyroid gland of young animals - calves not older than 12 months of age or pigs. The isolated peptides have a tissue-specific effect on thyroid cells, restoring metabolism and normalizing their functional activity.
THYREOGEN® is produced in tablets or capsules containing 10 mg of active peptides.
THYREOGEN® was administered to patients orally 10-15 minutes before meals, 1-2 capsules 2 times a day for 20 days, depending on the severity of the pathological process.
Clinical trials of THYREOGEN® were carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS, in patients with primary hypothyroidism in the period from November 2005 to January 2006.
Primary hypothyroidism is one of the age-related disorders of the thyroid gland. In the pathogenesis of primary hypothyroidism, a change in the gland tissue or inhibition of the synthesis of thyroid hormones due to infectious diseases, trauma, or spontaneous destruction of the thyroid gland comes to the fore (3, 4).
Drug treatment of primary hypothyroidism includes the use of the following drugs (1, 2):
- Thyroid hormones - thyroidin, thyroxine, triiodothyronine;
- Vitamins B6, B12;
- etc.

CLINICAL CHARACTERISTICS OF PATIENTS

The study involved 25 patients with primary hypothyroidism, including 11 men and 14 women aged 56 to 67 years. The control group consisted of 19 patients, including 7 men and 12 women. Patients in both groups complained of rapid fatigue, drowsiness, memory impairment, frequent headaches, and dizziness. In most cases, signs of thyroid atrophy were detected by palpation.
All patients previously received symptomatic therapy for the clinical manifestations of this disease. Patients in the control group were prescribed conventional means. In addition to conventional drugs, patients of the primary group received THYREOGEN® 1-2 capsules 2 times a day before meals for 20 days.

RESEARCH METHODS

The patients' complaints were assessed in dynamics, a general clinical examination of blood and urine, and a biochemical study of blood on the REFLOTRON apparatus (Boehringer Mannheim, Germany) were carried out. Ultrasound examination of the thyroid gland was performed using an ultrasound machine (ALOKA, Japan), electrocardiography - using a CARDIOTEST EK-51 apparatus (Hellinge, Germany).
The content of hormones T3 and T4 in blood serum was determined by radioimmunoassay. The radioactivity of the samples was counted on a Tracor Analytic 1285 counter (USA-Holland).

RESEARCH RESULTS

As a result of the studies, it was found that the use of THYREOGEN® contributed to the improvement of the clinical manifestations of the disease in 78% of cases, and the most significant effect was observed in persons of the older age group with pronounced signs of thyroid atrophy. While taking THYREOGEN®, the patients noted increased working capacity, decreased frequency and intensity of headaches, and decreased pain in the heart region.

Influence of THYREOGEN® on the level of thyroid hormones in blood serum in patients with primary hypothyroidism.

Table 1

Indicators	Before Treatment	After Treatment with Conventional Means	After Treatment with Thyreogen®
T3, (nmol/l)	0,38±0,03	1,12±0,06	1,58±0,07*
T4, (nmol/l)	38,8±5,4	55,1±4,3	87,5±6,2*

* P <0.05 - significant compared with the indicator in the control group patients.

In the study of objective indicators, normalization of ECG parameters was observed. Attention is drawn to the fact that the indicators of the secretory function of the thyroid gland remained at the achieved level for 3-5 months after the course of treatment with the use of THYREOGEN®. The restoration of the level of thyroid hormones within the physiological norm was noted (Table 1), which indicates a stabilizing effect of the drug on the cellular metabolism of the gland and a regulatory effect on metabolic processes.

Thus, the obtained results of a clinical study of the drug indicate the effectiveness and appropriateness of the use of THYREOGEN® in the complex treatment and prevention of thyroid dysfunctions of various origins.

Clinical study of THYREOGEN® revealed no side effects or contraindications. The drug does not cause complications or drug dependence.

The studied ready-made form of THYREOGEN® is convenient for inpatient, outpatient, and at-home use.

THYREOGEN® can be used for therapeutic and prophylactic purposes in the form of a biologically active food supplement as an adjuvant in combination with any means of symptomatic and pathogenetic therapy used to treat diseases caused by dysfunction of the thyroid gland of various origins.

CONCLUSION

The biologically active food supplement THYREOGEN® has a normalizing effect on the metabolism of thyroid cells.

THYREOGEN® is well tolerated by patients when taken orally, has no side effects, has no contraindications, and can be used as a therapeutic and prophylactic biologically active food supplement.

REFERENCES

1. Belousov Y.B., Moiseev V.S., Lepakhin V.K. Clinical Pharmacology and Pharmacotherapy: A Guide for Physicians. - M.: the Universe, 1993. -- 398 p.
2. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
3. Geriatric manual / Ed. D.F. Chebotarev, N.B. Mankovsky. – M.: Medicine, 1982. – 544 p.
4. Tepperman J., Tepperman H. Physiology of metabolism and the endocrine system: Translation from English - M.: Mir, 1989. -- 656 p.

RECOMMENDATIONS FOR USE

THYREOGEN® is recommended to restore thyroid function in acute and chronic thyroid lesions. As a prophylactic agent, it is advisable to use in areas endemic to thyroid diseases. It is also recommended for the elderly to maintain thyroid function.
The drug is taken 10-15 minutes before meals, 1-2 tablets or capsules 2 times a day for 20 days.
It is recommended to repeat the course of treatment in 3-6 months.
It is advisable to recommend THYREOGEN® for therapeutic and prophylactic use and industrial production.
Store in a dry place protected from light at a temperature of +2 to +25 oC.
Release form: 20 or 60 capsules of 0.2 g.
Expiration date: 5 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Cerluten®

Report on the results of clinical studies of the biologically active food supplement **Cerluten®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement CERLUTEN® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the brain tissue of young animals - calves up to 12 months of age or pigs.
CERLUTEN® is available in capsule form with an active ingredient content of 10 mg.
CERLUTEN® peptides regulate metabolic processes in brain cells, increase the brain's reserve capacity, have a beneficial effect on the adaptation processes of the body in extreme conditions, have antioxidant properties, and regulate the processes of peroxidation in the cerebral cortex. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This allows us to assume the effectiveness of the use of CERLUTEN® to restore the functions of the central nervous system in case of disorders of various origins.
Treatment of diseases of the central nervous system is of particular relevance since they entail a violation of social adaptation and disability of patients (2).
Currently, in the treatment of patients with diseases of the central nervous system, taking into account the pathogenetic mechanisms, the following traditional therapeutic agents of various directions of action are mainly used (1, 3):
- Influence on metabolism and integrative functions of the brain - cerebrolysin, piracetam, encephalolysate;
- Normalization of cerebral and systemic circulation - stugeron, cavinton;
- Relief of psychopathological manifestations - meridin, amitriptyline;
- Correction of changes in the bioelectric activity of the brain - phenobarbital, Konvulex;
- Impact on liquorodynamic disturbances - veroshpiron, furosemide;
- Prevention and inhibition of the development of adhesions - aloe, lidase;
- Correction of immunopathological reactions - levamisole, tavegil.
Clinical trials of CERLUTEN® were carried out in the period from October 2005 to February 2006 at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS, in 48 patients with various diseases of the central nervous system: long-term consequences of traumatic brain injury (the duration of the trauma was from 1 to 10 years), conditions after a stroke, vascular encephalopathy, and decreased mental performance, memory, and attention. In addition to conventional drugs, patients of the primary group received CERLUTEN® 1-2 capsules 2-3 times a day before meals for 10-20 days, depending on the severity of the pathological process. The distribution of patients by nosological forms, sex, and age is shown in Table 1.
The control group consisted of 37 similar patients who received only conventional treatment.
All patients had previously received drugs of symptomatic and pathogenetic action, with the use of which a short-term therapeutic effect was noted, requiring an increase in the dose of drugs for the course of treatment and their prolonged use.

Distribution of patients by nosological forms, sex and age.

Table 1

Diagnosis	Age	Total:		Total:		Total:	
		Control Group	Primary Group	Control Group	Primary Group	Control Group	Primary Group
Long-term consequences of traumatic brain injury	32-58	5	8	2	2	7	10
Conditions after a stroke	51-68	4	4	4	5	8	9
Vascular encephalopathy	52-73	5	6	7	11	12	17
Manifestations of reduced mental performance, memory, and attention	43-65	6	7	4	5	10	12
Total:		20	25	17	23	37	48

RESEARCH METHODS

The effectiveness of CERLUTEN® was assessed by the dynamics of subjective indicators and objectively using the methods of correction test and electroencephalography (EEG).

RESEARCH RESULTS

After using CERLUTEN® in patients of the primary group, an excellent clinical result was observed in 64.6% of cases, satisfactory - in 22.9%, no positive effect - in 12.5% of cases (in the control group - Table 2). There was no negative effect from CERLUTEN® on the condition of the patients.

The efficacy of CERLUTEN® in patients with diseases of the central nervous system.

Table 2

Treatment Results	Patient Group			
	Treatment Using Conventional Means		Treatment Using CERLUTEN®	
	Abs.	%	Abs.	%
Good	10	27,0	31	64,6*
Satisfactory	15	40,5	11	22,9
Unsatisfactory	12	32,5	6	12,5*
Total:	37	100	48	100

* P <0.05 compared with the indicator in patients after treatment with conventional means.

When comparing the subjective indicators of the state of patients before and after the use of CERLUTEN®, it was found that the number of health complaints decreased by 2-3 times. Patients noted an improvement in memory, intelligence, a decrease in the intensity and duration of headaches, the appearance of emotional balance, volitional qualities, and a sense of rest after a night's sleep (Table 3).

In patients with the consequences of traumatic brain injury and stroke, there was a moderate regression of focal symptoms, improved speech function with motor and sensory aphasia, and decreased muscle spasticity.
Comparative assessment of the influence of CERLUTEN® and other treatment methods on the integral function of the brain - attention and bioelectrical activity of the brain were studied using a corrective test and electroencephalography, respectively.

Influence of CERLUTEN® on the subjective indicators of the health status of patients.

Table 3

Indicator	Before Treatment, %	After Treatment using Conventional Means, %	After Treatment using Cerluten®
Headaches	76,6	47,2#	34,1#
Sleep disturbance	54,9	34,0#	24,3#
Emotional lability	75,8	43,0#	21,4*#
Memory impairment	54,5	45,2	28,5*#
Absent-mindedness	48,7	43,9	14,6*#
Fast fatiguability	72,0	53,2#	32,4*#

# P <0.05 compared with the indicator in patients before treatment;
* P <0.05 compared with the indicator in patients after treatment with conventional means..

Influence of CERLUTEN® on the dynamics of indicators of performing the correction test by patients with diseases of the central nervous system.

Table 4

Examined group	Quantity of viewed characters	Quantity of mistakes
Healthy	1835,2±83,7	7,15±1,01
Patients before treatment	1143,7±75,4	18,12±0,93
Patients after treatment with conventional means	1573,8±67,5*	11,1±0,86*
Patients after treatment with CERLUTEN®	1682,6± 62,8*#	8,67± 0,96*#

* P<0.05 compared with the indicator in the group of patients before treatment;
# P<0.05 compared with the indicator in the group of patients after treatment with conventional means.

The results of performing a correction test by patients after treatment by various methods are presented in Table 4. The best results were obtained in the primary group patients when analyzing the dynamics of performing the correction test before and after treatment compared to patients in the control group. As can be seen from the table, in patients after treatment with CERLUTEN®, the number of viewed signs significantly increased, and the number of errors decreased. This was expressed in the absence of sharp fluctuations in the number of viewed characters for equal periods, the presence of a period of «workability» by the middle of the task, and a gradual decrease in the curve by the end of the task, which indicates greater stability of attention after treatment.
To assess the effect of CERLUTEN® on the bioelectrical activity of the brain, a visual analysis of EEGs was performed with their distribution by type and the calculation of the alpha index before and after treatment. EEG was performed selectively in patients with the most pronounced manifestations of pathological processes. The research results are presented in Table 5.

The influence of CERLUTEN® on the characteristics of the types of electroencephalograms in patients with diseases of the central nervous system.

Table 5

Surveyed Group	Type of EEG					
	III		IV		V	
	Before Treatment	After Treatment	Before Treatment	After Treatment	Before Treatment	After Treatment
After Treatment with Conventional Means	9	7	11	9	13	9
After Treatment with Cerluten®	11	7	10	6	15	7

Before treatment, pathological (III, IV, V) types of EEG prevailed in the examined patients in different groups. Type III EEG was characterized by the presence of a so-called non-dominant curve at a low amplitude level (no higher than 30-35 μV), the presence of irregular alpha activity, or even its absence. The IV type of EEG was characterized by a highly emphasized regularity of rhythms, blurring of zonal differences. The V type of EEG was characterized by irregular slow activity with an amplitude above 35 μV, sharp waves, paroxysmal discharges.
The most pronounced changes in the brain's bioelectric activity were observed in patients after treatment with CERLUTEN®. First of all, this was manifested on the EEG in a clearer modulation and restoration of zonal differences in the alpha rhythm, a weakening of the severity of irritative processes, in some cases - the disappearance of paroxysmal discharges.

Influence of CERLUTEN® on the dynamics of changes in the alpha-index in patients with diseases of the central nervous system.

Table 6

Examined Group	Alpha Index	
	Before Treatment	After Treatment
Healthy	55,1±3,9	-
Patients Treated with Conventional Means	33,6±3,7	41,3±4,2
Patients Treated with Cerluten®	34,0±4,1	47,9±3,7*#

* P<0.05 compared with the indicator in the group of patients before treatment;
# P<0.05 compared with the indicator in the group of patients after treatment with conventional means.

In addition to visual EEG assessment, the alpha index was calculated in patients before and after treatment (Table 6). It was found that under the influence of the treatment, there was a significant increase in the alpha index in the patients of the study groups. The value of the alpha index was significantly higher in the group of patients after treatment with CERLUTEN® as compared to the values in other groups. However, the degree of change in the alpha index in patients receiving different treatments was not the same.

CONCLUSION

Based on the data obtained, it is legitimate to conclude that the inclusion of reserve capacities of the cerebral cortex with the help of CERLUTEN® improves the integral functions of the brain.
Thus, the clinical study results indicate the effectiveness and feasibility of using CERLUTEN® in the complex treatment and prevention of diseases of the central nervous system of various origins.
CERLUTEN® does not cause side effects, complications, or drug dependence; clinical trials have identified no contraindications.
CERLUTEN®can be used for therapeutic and prophylactic purposes, combined with any means of symptomatic therapy used in neurological practice (vascular, nootropic, absorbable, anticonvulsant, vitamins, etc.).

REFERENCES

1. Kovalev G.V. Nootropic medicines. – Volgograd: Nizh.-Volzh. Publishing house, 1990. – 368 p.
2. Treatment of nervous diseases: Translated from English/ Edited by V.K.Viderholt. – M.: Medicine, 1984. – 560 p.
3. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.

RECOMMENDATIONS FOR USE

CERLUTEN® is recommended to accelerate the recovery of brain functions after traumatic brain injury, strokes, intellectual-mnestic disorders, exposure of the body to various extreme factors. It is also recommended for the elderly to maintain mental performance.
CERLUTEN® is recommended to be taken 10-15 minutes before meals, 1-3 tablets or capsules 2-3 times a day for 10-20 days.
A second course is advised in 3 - 6 months.
There were no contraindications or side effects observed when using CERLUTEN®.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Chelohart®

Report on the results of clinical studies of the biologically active food supplement **Chelohart®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement CHELOHART® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the tissues of the heart of young animals - calves not older than 12 months of age or pigs.
CHELOHART® is available in capsules with an active substance content of 10 mg.
CHELOHART®'s peptides regulate metabolic processes in myocardial cells, increase the reserve capacity of myocardiocytes, have a beneficial effect on the adaptation processes of the body in extreme conditions, and have antioxidant properties, regulating the processes of peroxidation in the myocardium. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This allows us to assume the effectiveness of using CHELOHART® to restore the functions of the heart in case of disorders of various origins.
Disorders of myocardial metabolism associated with oxygen deficiency underlie the development of various forms of ischemic heart disease, is a common link in the pathogenesis of cardiomyopathies and causes various cardiac disorders. The pathological process is based on a violation of the correspondence between the heart's need for blood supply and the functioning of the vascular system. Insufficient blood supply to the myocardium is most often caused by atherosclerosis of the coronary vessels, one of the most common age-related pathologies (1). Of particular concern to clinicians in recent decades is the emergence of this age-related pathology in people of an increasingly young age, which leads to the «rejuvenation» of myocardial infarction and an increase in the risk of developing its complications. Ischemic heart disease is one of the most common causes of disability of patients and mortality among the population of developed countries.
In the conservative treatment of patients with coronary heart disease, taking into account the pathogenetic mechanisms, the following traditional therapeutic agents of various directions of action are mainly used (1, 2):
- Vasodilators (nitroglycerin, nitrong, erinit);
- Calcium antagonists (verapamil, fenigidin);
- β-blockers (anaprilin, trazikor);
- Drugs that weaken adrenergic effects on the heart (cordaron);
- etc.

CLINICAL CHARACTERISTICS OF PATIENTS

A clinical study of the effectiveness of using CHELOHART® was carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology from May to November 2011.
The clinical study involved 32 patients with ischemic heart disease - exertional angina of functional class I and II - aged 46 to 72 years, including 18 men and 14 women. Disease duration ranged from 2 to 9 years.
Patients complained of rapid fatigability, decreased performance, weakness, tinnitus, dizziness, palpitations, shortness of breath, recurrent pain in the heart, limited physical activity, and the onset of chest pain attacks with characteristic irradiation to the left shoulder, left arm, and interscapular space. 19 patients (59.4%) diagnosed with exertional angina pectoris of the Ist class noted the development of seizures only with great physical activity; the attacks were quickly stopped after the use of nitroglycerin. In 10 patients (31.2%) diagnosed with exertional angina pectoris of the IInd class, pain attacks behind the sternum occurred when walking at a distance of more than 500 m and climbing stairs. At the same time, the patients noted a gradual increase in the frequency of attacks, which required an increase in the dose of nitro drugs.
On the electrocardiogram, an objective examination in 26 patients (81.2%) revealed signs of impaired coronary circulation during stress tests: a decrease in the S-T segment, a smoothed or negative T wave in the standard and corresponding chest areas.
Analysis of the general clinical and biochemical blood tests did not reveal significant deviations from normal values in each age group.
The patients were divided into 2 groups. The primary group included 22 patients, including 14 men aged 46 to 64 years old and 8 women aged 51 to 72 years old, who, in addition to conventional meth-

ods of treatment, were prescribed a course of CHELOHART®, 1 capsule 2 times a day with meals for 30 days.
The control group consisted of 10 patients (6 men aged 47 to 66 years and 4 women aged 50 to 69 years) who were prescribed only conventional treatment: long-acting nitrates, β-blockers, corinfar, corvalol, motherwort tincture, and other sedatives (2, 3).

RESEARCH METHODS

The study of the effectiveness of the use of CHELOHART® was carried out based on generally accepted research methods. Patients' complaints were assessed in dynamics, general clinical and biochemical blood tests, ultrasound examination of the heart, electrocardiography, a dosed exercise test on a bicycle ergometer were carried out according to the method of step-by-step increasing intermittent activity.

RESEARCH RESULTS

The study results of the dynamics of changes in subjective indicators showed that in patients taking CHELOHART®, the number of complaints about the general condition, shortness of breath, recurring pain in the heart, and a feeling of rapid heartbeat decreased. The frequency and duration of angina attacks significantly reduced. In 56% of patients, it was possible to reduce by half the daily dose of nitrates of prolonged action against the background of a persistent decrease in the attacks of chest pain in comparison with the initial level before treatment (Table 1).

Dynamics of subjective indicators in patients with coronary heart disease. Table 1

Complaints	Patient Groups			
	After treatment with conventional means, abs. (%)		After treatment with CHELOHART®, abs. (%)	
	Improvement	Without Improvements	Improvement	Without Improvements
Recurrent pain in the heart region	4 (40%)	6 (60%)	15 (68,2%)*	7 (31,8%)*
Dyspnea	6 (60%)	4 (40%)	16 (72,7%)*	6 (27,3%)*
Weakness	7 (70%)	3 (30%)	16 (72,7%)*	6 (27,3%)*
Dizziness	6 (60%)	4 (40%)	12 (54,5%)	10 (45,5%)
Headaches	5 (50%)	5 (50%)	15 (68,2%)*	7 (31,8%)*
Noise in ears	5 (50%)	5 (50%)	14 (63,6%)	8 (36,4%)
Palpitations	6 (60%)	4 (40%)	17 (77,3%)*	5 (22,7%)*

* p <0.05 compared with the indicator in patients after treatment with conventional means.

The study of the dynamics of changes in mineral metabolism showed that in patients of both groups, the potassium content in the blood plasma and calcium in the blood serum increased, approaching normal values. There was no significant difference in indicators in patients of the primary and control groups. However, the indicators after treatment were better in patients of the primary group who took CHELOHART®than in patients in the control group. The magnesium content in the blood serum remained within the normal range before and after treatment in patients of both groups (Table 2).

Dynamics of changes in the indicators of mineral metabolism in the blood of patients with coronary heart disease.

Table 2

Indicator	Norm	Patients Treated with Conventional Means		Patients who additionally received Chelohart®	
		Before Treatment	After Treatment	Before Treatment	After Treatment
Potassium, mmol/l	3,4-5,3	3,13±0,6	3,48±0,4	3,10±0,4	3,52±0,5
Calcium, mmol/l	2,3-2,75	2,22±0,03	2,36±0,06	2,23±0,05	2,41±0,06
Magnesium, mmol/l	0,7-1,2	0,83±0,04	0,88±0,06	0,84±0,07	0,90±0,05

According to veloergometry data, the appearance of an attack of angina pectoris at the height of activity after using CHELOHART® was observed reliably 1.9 times less often than before treatment, while in patients of the control group - only 1.4 times (Table 3). After complex treatment with CHELOHART®, 54.5% of patients achieved a submaximal heart rate (HR) at the height of the threshold activity, while in the control group - only 40% (before treatment - 21.9% of patients in both groups).
The tolerance assessment was carried out according to the threshold power value and the total amount of work performed. As an indicator of positive antianginal treatment, tolerance to physical activity was significantly higher in patients of the primary group after taking CHELOHART® compared with indicators before treatment. However, the difference with indicators in patients in the control group was insignificant.
To assess the efficiency of the cardiovascular system, the energy expenditure index was calculated. A 1.6-fold decrease in the index after using CHELOHART® testified to a more economical expenditure of energy reserves of the heart due to a decrease in myocardial oxygen demand during work (in patients of the control group - by a factor of 1.3), which was reflected in a significant increase in the index of maximum oxygen consumption by 16% in patients of the primary group (in the control group - by 11%) compared with the indicator before treatment.

Dynamics of veloergometry indicators in patients with ischemic heart disease.

Table 3

Indicator	Before Treatment	After Treatment with Conventional Means	After Treatment with Chelohart®
The frequency of angina attacks,%	68,8	50*	36,4*#
Achievement of submaximal heart rate,%	21,9	40*	54,5 *#
Veloergometry threshold power, W/min	96,9±4,6	115,2±5,4	119,3±4,6*
Total work, kgm	2830±118	3457±110*	3673±119*
Energy cost index, units	15,8±1,4	11,9±2,4*	9,6±2,1*
Maximum oxygen consumption index, units	1,3±0,03	1,44±0,05*	1,49±0,04*

* p <0.05 compared with the indicator in patients before treatment;
# p <0.05 compared with the indicator in patients after treatment with conventional means.

CONCLUSION

Thus, as a result of the study, it was found that CHELOHART® has a pronounced effect on the contractile function of the myocardium in patients with ischemic heart disease. An increase in patients' tolerance to stress tests indicates the anti-ischemic effect of the drug and an improvement in mineral metabolism indicators - a positive impact on metabolic processes in myocardial cells. In addition, we observed a significant decrease in the index of energy costs due to an increase in the index of maximum oxygen consumption.
When conducting a clinical study of CHELOHART®in the elderly, no side effects, complications, or drug dependence were observed. Do not use the product in case of individual intolerance to its components.
Thus, the results of the study indicate the advisability of including CHELOHART® in the complex treatment of patients with angina pectoris of the I-II functional classes, as well as its use for the prevention of age-related pathology of the cardiovascular system, which should be carried out in courses of 1-2 capsules 2 times a day during 30 days. The course should be repeated 2-3 times a year.

REFERENCES

1. O. V. Korkushko- Age-related changes in the autonomic regulation of the heart rate in healthy elderly and senile people / O.V. Korkushko, V.B. Shatilo, G.M. Butenko // Physiol. zhurn. - 1988. - Issue. 34, No. 1. - S. 12-17.
2. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO "Gamta", 1993.
3. Metelitsa V.I. - Cardiologist's Guide to Clinical Pharmacology. - M .: Medicine, 1980 .-- 304 p

RECOMMENDATIONS FOR USE

CHELOHART® is a complex of peptides obtained from the heart of young animals. The isolated peptides have a selective effect on myocardial cells, normalize metabolism in myocardiocytes, and regulate the functions of the heart.
In a clinical study, the effectiveness of CHELOHART® was established in the complex treatment of patients with cardiovascular pathology, including ischemic heart disease, for the restoration of myocardial functions after diseases of various origins, under the influence of extreme environmental factors, malnutrition, as well as aging.
Take1-2 capsules or tablets of CHELOHART® 1-2 times a day with meals. Duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.
Do not use in case of individual intolerance to the components, pregnancy, breastfeeding.
No side effectswere observed when using CHELOHART®.
Store in a dry, dark place at a temperature from +2 to +25 °C.
Release form: 20 capsules or tablets containing 10 mg of CHELOHART®.
Expiration date: 3 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Chitomur®

Report on the results of clinical studies of the biologically active food supplement **Chitomur®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement CHITOMUR® contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the tissues of the bladder wall of young animals - calves notolder than 12 months of age or pigs.
CHITOMUR® is available in capsules with an active substance content of 10 mg.
Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. CHITOMUR® peptides regulate metabolic processes in the bladder wall cells, increase their reserve capacity, have a beneficial effect on the body's adaptation processes in extreme conditions, have antioxidant properties, and regulate the processes of peroxidation in the tissues of the bladder wall. This allows us to assume the effectiveness of the use of CHITOMUR® to restore the functions of the bladder in case of disorders of various origins.
Among the diseases most common in the elderly, the pathology of the bladder and urinary system stands out, significantly impairing the quality of life of patients and aggravating the course of concomitant pathology. With age, the number of patients with various disorders of the lower urinary tract function increases significantly, especially in the case of an overactive bladder (OAB). The diagnosis is made without any hormonal, metabolic, or other apparent diseases (urinary tract infection, bladder cancer, prostate adenoma, etc.) that can cause the symptoms.
The risk of overactive bladder syndrome increases with age. The critical age is over 60 - among older people of this age, the prevalence of OAB is at its maximum. The increased risk of OAB for men is explained, in addition, by benign prostatic hyperplasia, signs of which are present to one degree or another in about half of men aged 60+ years. Nevertheless, the absence of hyperplasia does not exclude the presence of age-related changes in the bladder, which are almost identical in men and women.
It is believed that the postmenopausal period is also associated with an increased risk of developing OAB. More than 60% of postmenopausal women suffer from urinary dysfunction. However, the role of sex hormones is not clear. The results of the use of hormone replacement therapy in these patients are ambiguous, and instead of improvement, it can lead to a worsening of OAB symptoms. Thus, a number of anatomical and physiological changes accompanying aging may predispose to the development of OAB symptoms. Regardless, urinary incontinence should not be considered a natural sign of aging. In addition, specific functional impairments such as limited mobility, dysfunction of the upper limbs, and decreased vision can aggravate the course of OAB. It should be kept in mind that pharmacological drugs used for concomitant diseases can also play a role. For example, diuretics can significantly increase urinary frequency and mimic OAB symptoms.
Treatment of dysfunction of the bladder depends on the etiology of the pathological condition. In chronic cystitis, antibiotic therapy is prescribed; with detrusor dysfunction, drugs of the atropine group are prescribed; in case of neurogenic dysfunction of the bladder, M-anticholinergics (oxybutin, tolterodine, darifenacin) are prescribed.

CLINICAL CHARACTERISTICS OF PATIENTS

A clinical study of the effectiveness of the use of CHITOMUR® was carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology in the period from March to November 2011. The study involved 28 men aged 45 to 62 with a diagnosis of benign prostatic hyperplasia (BPH) and 31 women aged 48 to 56 with a diagnosis of overactive bladder (OAB). All patients complained of dysfunction of urination.

Distribution of patients by nosological forms and age. Table 1

Diagnosis	Age	Number of Patients	
		Control Group	Primary Group
Benign prostatic hyperplasia	45-62		
Overactive bladder	48-56	9	22
Total:		19	40

* p <0.05 - significant compared to the indicator before treatment.

In addition to conventional means, patients of the primary groups (18 men and 22 women) were prescribed CHITOMUR® 1 capsule 2 times a day with meals for 30 days. Patients in the control groups (10 men and 9 women) received only conventional treatment. The distribution of patients by groups is shown in Table 1.
The effectiveness of the use of CHITOMUR®was assessed based on the dynamics of complaints of patients, general clinical examination of blood and urine, the biochemical study of blood, the degree of abdominal pressure during urination, and the nature of the urine stream, fluorometric index.

RESEARCH RESULTS

The results of a clinical study of CHITOMUR® showed that pollakiuria (increased frequency of urination) altogether ceased to bother 88.3% of patients with BPH. In 93.2% of patients, the need for nocturnal urination disappeared. Stranguria (difficulty urinating) ceased to bother 74.8% of patients, 26.7% of patients noted an increase in the urine stream and relief during the act of urination.
The dynamics of the study results in patients with BPH before and after the course of treatment with CHITOMUR® is presented in Table 2.

Influence of CHITOMUR® on the state of urodynamics in patients with benign prostatic hyperplasia. Table 2

Indicator	Before Treatment	After Treatment with Conventional Methods	After Treatment with Chitomur®
Time of urinary retention	4,5±0,6	3,4±0,4*	2,2±0,3*
Number of urinations: **- in the daytime** **- in nighttime**	 8,7±0,2 3,7±0,3	 7,2±0,3* 2,9+0,2	 6,3±0,1* 2,0+0,4
Abdominal pressure, (points)	3,2	2,7	2,3
The nature of the stream of urine, (points)	3,4	2,5*	2,2*
Average urination rate, (ml/s)	13,5±1,3	15,1±1,6	19,4±1,4*
Maximum speed of urination, (ml/s)	17,2±1,8	19,1±1,5	21,4±1,6
Maximum speed of urination, (ml/s)	6,4±0,1	5,4±0,2*	4,4±0,4*

* p <0.05 - significant compared to the indicator before treatment.

The condition of patients with BPH after treatment with CHITOMUR® was characterized by an improvement in subjective and objective indicators of urodynamics.
It should be noted that uroflograms recorded after treatment in patients with BPH stages I and II showed the restoration of the basic parameters of urination to normal values. At stage III of the disease, this was prevented by a decrease in the elasticity of the bladder neck due to sclerotic changes in the tissue of the prostate gland. Still, a noticeable increase in the urine stream was observed in such patients.
The patients' assessment of their bladder condition significantly improved. In women with climacteric syndrome, accompanied by an overactive bladder, the use of CHITOMUR® achieved a 38% reduction in urgency and incontinence episodes by 43%. The degree of discomfort due to imperative symptoms decreased 1.8 times, the degree of anxiety decreased by 57%, and satisfaction with treatment reached 78%. Thus, according to the patients' self-esteem, the decrease in anxiety caused by the symptoms of urinary dysfunction is 1.8 times, comes ahead of the very positive dynamics of these symptoms, which indicates a predominant improvement in the quality of life of women as a result of treatment.
A month after the course of treatment using CHITOMUR®, all patients retained the improvement in symptoms. After discontinuation of the drug, the bladder capacity increased by 10-20% with various urges to urinate, which is explained by a decrease in detrusor ischemia, which plays a significant role in the pathogenesis of OAB.
Thus, the results of this study indicate the therapeutic efficacy of CHITOMUR® and the practicality of its use in the complex treatment of dysuric disorders of various origins, including in diseases of the prostate gland in men and women with symptoms of an overactive bladder.
CHITOMUR® does not cause side effects, complications, or drug dependence and can be used for therapeutic and prophylactic purposes, combined with any means of symptomatic therapy used in urological practice (antibacterial agents, antispasmodics, vascular and hormonal drugs, vitamins, etc.)

CONCLUSION

Biologically active food supplement CHITOMUR® has a regulating effect on the functional activity of the cells of the wall and detrusor cells of the bladder and helps normalize urination function.
CHITOMUR®is well tolerated when taken orally, has no side effects, and can be used as a therapeutic and prophylactic biologically active food supplement.
CHITOMUR®is recommended for patients with impaired urination function of various origins - orally during meals, 1-2 capsules or tablets 2 times a day for 30 days. It is recommended to repeat the course of treatment in 3-6 months.

REFERENCES

1. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO "Gamta", 1993.
2. Guide to Andrology / Ed. O. L. Tiktinsky. - L.: Medicine, 1990. -- 416 p.
3. Sexopathology: A Handbook / Ed. G.S. Vasilchenko. - M.: Medicine, 1990. -- 576 p.

RECOMMENDATIONS FOR USE

CHITOMUR® is a complex of peptides obtained from the bladder wall of young animals. The isolated peptides have a selective effect on the cells of the bladder wall, normalize their metabolism, and regulate the functions of the bladder.

In a clinical study, the effectiveness of CHITOMUR® was determined in the complex treatment of patients with dysfunction of urination of various origins, including in men with chronic prostatitis and prostatic hyperplasia and women with overactive bladder syndrome, to restore the functions of the bladder after past diseases of various origins, with exposure to extreme environmental factors, malnutrition, and aging.

Take 1-2 capsules or tablets of CHITOMUR® 1-2 times a day with meals. Duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.

Do not use in case of individual intolerance to the components, pregnancy, breastfeeding.

No side effects have been identified when using CHITOMUR®.

Store it in a dry, dark place at a temperature from +2 to +25 °C.

Release form: 20 capsules or tablets each containing 10 mg ofCHITOMUR®.

Expiration date: 3 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Endoluten®

Report on the results of clinical studies of the biologically active food supplement **Endoluten®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement ENDOLUTEN®contains a complex of low molecular weight peptides with a molecular weight of up to 5000 Da, isolated from the pineal gland tissues of young animals - calves up to 12 months age or pigs.
ENDOLUTEN® is available in capsules with an active substance content of 10 mg.
ENDOLUTEN®'s peptides regulate metabolic processes in neuroendocrine cells of various tissues, including the pineal gland, increasing the neuroendocrine system's reserve capacity, having a beneficial effect on the adaptation processes of the body in extreme conditions, and have antioxidant properties, which regulate the processes of peroxidation in various tissues. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. This allows us to assume the effectiveness of the use of ENDOLUTEN® for the restoration of neuroendocrine regulation in case of disorders of various origins.
According to experimental data, ENDOLUTEN® contributes to the normalization of neuroendocrine regulation of the body's main functions.
It is known that the age-related decrease in the functional activity of the pineal gland causes a disturbance of the mechanisms of interaction of the nervous, endocrine, and immune systems and contributes to the development of various diseases and pathological conditions. The impact of extreme environmental, climatic-geographical, professional, and psycho-emotional factors on the human body leads to neuroendocrine and immunological disorders that cause maladjustment disorders and psychosomatic diseases (3, 4, 5, 6).
The medical treatment of these diseases and pathological conditions includes the use of a wide variety of drugs, depending on the symptoms of the disease. However, the correction of these disorders is based on the prescription of certain medications (1, 2):
- Adaptogens (ginseng, extracts of Eleutherococcus, Leuzea, Rhodiolarosea, tinctures of aralia, zamanihi, saparal, pantocrine);
- Peptide immunomodulators (thymalin, taktivin, thymogen, myelopid);
- Pineal gland hormone - melatonin;
- Pineal gland peptides - epithalamin;
- Multivitamins;
- etc.

However, drugs have side effects and cannot be prescribed to prevent the listed pathological conditions. In this regard, developing new effective and safe means for prevention and increasing the effectiveness of treating patients with pathological conditions associated with impaired neuroendocrine regulation is an urgent problem.
Clinical trials of ENDOLUTEN® were carried out in 163 patients (including 48 men, 115 women) with dyshormonal myocardial dystrophy, physiogenic asthenia, and climacteric syndrome of mild and moderate severity in women, as well as in cancer patients after courses of radiation and chemotherapy, treated at the St. Petersburg Medical Center of the Institute of Bioregulation and Gerontology, SZO RAMS from January to August 2011. The distribution of patients by nosological forms, sex, and age is presented in Table 1.

Distribution of patients by nosological forms, sex and age. Table 1

Diagnosis	Age	Group	Male	Female	Total
Dyshormonal myocardial dystrophy	40-59	Control	-	10	10
		Primary	-	18	18
Physiogenic asthenia	18-42	Control	9	-	9
		Primary	14	-	14
Conditions after radiation and chemotherapy in cancer patients	48-76	Control	11	18	29
		Primary	14	26	40
Severe manifestations of climacteric syndrome	42-63	Control	-	16	16
		Primary	-	27	27
Total:			48	115	163

The patients were randomized into 2 groups for each nosological form: control groups consisted of 64 people who received conventional treatment for their diseases (1, 2). Patients receiving hormone replacement therapy were not included in the study.
In addition to the conventional treatment, patients of the primary groups were prescribed ENDOLUTEN® 1-3 capsules before meals 2-3 times a day for 15-30 days, depending on the severity of the pathological process.

RESEARCH METHODS

The study of the effectiveness of the use of ENDOLUTEN® was carried out based on generally accepted research methods. Patients' complaints were assessed in dynamics, general clinical examination of blood and urine, biochemical blood test, and electrocardiographic study were conducted. Peripheral blood lymphocytes' number and functional activity were assessed using immunological methods. The content of hormones (FSH and LH) in blood serum was determined by radioimmunoassay. A correction test and Luscher's test were used to assess psychophysiological parameters.

RESEARCH RESULTS

Negative manifestations of the climacteric period significantly reduce the working capacity of women of the most working-age. Therefore, the problem of finding new effective means that can reduce or completely neutralize pathological conditions in women in the postmenopausal period, preserving their health and high quality of life, is of particular relevance.

Influence of ENDOLUTEN®on the content of pituitary hormones in blood serum of patients with dyshormonal myocardial dystrophy. Table 2

Indicator	Norm	Before Treatment	After Treatment with Conventional Methods (Control Group)	After Treatment with Endoluten® (Primary Group)
FSH, (IU/ml)	1,5-45	89,3±3,5	71,6±6,3*	46,8±3,9*#
LH, (IU/ml)	2-17	28,1±1,9	25,7±2,4	16,4±1,4*#
Estradiol, (pmol/l)	110-734	65,4±5,2	79,1±4,2*	101,3±7,2*#

* p <0.05 - statistically significant compared with the indicator before treatment.
# p <0.05 - statistically significant in comparison with the indicator in patients of the control group.

In the process of using ENDOLUTEN® in patients with dyshormonal myocardial dystrophy, an improvement in the subjective indicators of the disease was noted, which was manifested in a decrease in pain attacks in the heart area, an increase in working capacity, and a normalization of the psychoemotional state.
While taking ENDOLUTEN®, there was a positive dynamics of the ECG. The study of the level of hormones in the blood serum of the patients of the primary group revealed a decrease in the initially elevated FSH content from 89.3 ± 3.5 IU/ml to 46.8 ± 3.9 IU/ml with a norm of 1.5-45 IU/ml, and in patients of the control group only up to 71.6 ± 6.3 IU/ml, which is significantly less than the indicator before treatment, but considerably higher than the norm (Table 2). The same tendency was found in the dynamics of changes in the LH content: in the patients of the primary group, under the influence of ENDOLUTEN®, the indicator decreased to a normal value, while in the control group, it significantly decreased compared to the indicator before treatment, but remained substantially higher than the norm. The estradiol content, initially reduced considerably in patients of both groups, increased from 65.4 ± 5.2 pmol/l to 101.3 ± 7.2 pmol/l and approached the normal value (110-734 pmol/l). In contrast, in the control group patients, this indicator increased only to 79.1 ± 4.2 pmol/l.
The study made it possible to reveal the corrective effect of ENDOLUTEN® on hormonal imbalance, contributing to the normalization of metabolism in myocardial tissues, which correlated with an improvement in the clinical picture of the disease.
The same tendencies in the normalization of the hormonal status were observed in patients with mild and moderate climacteric syndrome: under the influence of ENDOLUTEN®, the balance of pituitary hormones was restored, which correlated with the leveling of the main symptoms. The results of a study of the effectiveness of the use of ENDOLUTEN® for the treatment of women with climacteric syndrome are shown in Table 3.
As can be seen from the data in Table 3, in the process of using ENDOLUTEN® in patients with the climacteric syndrome, an improvement in subjective indicators was noted, which was manifested in a significant decrease in pain attacks in the heart, dizziness, a feeling of «fading» of the heart, and improved sleep compared to those in patients before treatment. In addition, the number of complaints of tachycardia attacks, sweating, hot flushes to the head and upper body, and fluctuations in blood pressure decreased significantly compared with the indicators in patients before treatment and with those in patients after treatment using conventional means (Table 3). Patients noted a significant increase in performance after using ENDOLUTEN®, which they associated with the normalization of the psychoemotional state. It is noteworthy that a stable aftereffect characterized the effect of the drug. So, 1-2 months after the end of the course of ENDOLUTEN®, symptoms such as dizziness, tinnitus, general weakness, increased fatigue, and sleep disturbance did not return.

Dynamics of subjective indicators in patients with climacteric syndrome.

Table 3

Indicator	Number of patients, (%)		
	Before Treatment	After Treatment with Conventional Means (Control Group)	After Treatment with Endoluten® (Primary Group)
Hot flushes in the head and upper body	78,0	59,4*	26,2*#
Increased sweating	72,6	54,1*	23,2*#
Headaches	63,4	48,3	35,2*
Changes in blood pressure	53,1	37,3	26,2*#
Pain in theheart region	59,4	38,8*	23,5*#
Tachycardia attacks	68,4	45,1*	22,4*#
Dizziness	43,8	31,2*	26,3*
Weakness	61,5	46,4	30,0*
Feeling of "sinking" heart	52,8	27,2*	24,6*
Fast fatiguability	85,2	53,9*	32,6*#
Reduced performance	86,8	56,2*	38,4*#
Irritability	93,1	62,5*	36,1*#
Tearfulness	54,2	34,8*	22,3*#
Sleep disturbance	76,8	47,6*	22,1*#
Decreased memory and attention	57,1	43,2	32,7*

* p <0.05 compared with the indicator in patients before treatment;
#p <0.05 compared with the indicator in patients after treatment with conventional means.

ENDOLUTEN® was also used in the complex therapy of men with physiogenic asthenia. The drug had a pronounced corrective effect on the dynamics of subjective indicators. Men suffering from physiogenic asthenia complained of general weakness, dizziness, increased fatigue, reduced efficiency, and sleep disturbance. The additional inclusion of ENDOLUTEN® in the treatment regimen of this category of patients led to the relief of subjective symptoms, which contributed to a rapid and effective improvement in the general condition, while in the control group patients who received only conventional therapy, the improvement in their condition occurred exceptionally slowly, and after the cessation of the course of treatment subjective neurological symptoms returned. It is important to note that when ENDOLUTEN® was used, a pronounced aftereffect was observed: after discontinuation of the drug, the improvement in the patients' condition continued and persisted during the observation period - at least 1-3 months.
Thus, the use of ENDOLUTEN® is a promising direction in the treatment of pathological conditions associated with impaired neurovegetative regulation, including climacteric syndrome, physiogenic asthenia, vegetative-vascular dystonia, and other psychovegetative disorders.
ENDOLUTEN® was also used in cancer patients, mainly in hormone-dependent tumors (breast cancer, cervical cancer, other localizations), after surgical treatment, and courses of radiation

and chemotherapy as an adjunct to conventional complex treatment. Before treatment, all patients showed a change in the blood count, which was expressed primarily in leukopenia and lymphocytopenia. Patients complained of poor health, decreased muscle tone, reduced appetite, and apathy.

Influence of Endoluten®on immunological blood parameters of cancer patients.

Table 4

Indicator	Norm	БPatients		
		Before Treatment	After Treatment with Conventional Means (Control Group)	After Treatment with Endoluten® (Primary Group)
Leukocytes, x109/l	4,0-8,8	3,14±0,11*	4,14±0,21	4,87±0,32#
Lymphocytes, x109/l	1,96±0,06	0,89±0,14*	1,42±0,18#	1,78±0,13#^
T-lymphocytes,x109/l	1,05±0,05	0,39±0,02*	0,61±0,05*#	0,79±0,04#^
"Active" T-lymphocytes (A-ROCK),x109/l	0,59±0,04	0,29±0,07*	0,35±0,06*	0,39±0,01*
RTML with KonA,%	59,1±1,7	91,5±3,8*	74,7±4,3*#	64,6±4,3#^
B-lymphocytes (EAC-ROCK), x109/l	0,53±0,04	0,30±0,06*	0,34±0,07	0,37±0,02

* p <0.05 - statistically significant compared with the normal indicator;
# p <0.05 - statistically significant compared with the indicator before treatment;
^p <0.05 - statistically significant compared with the indicator in the control group.

When ENDOLUTEN® was used in cancer patients of the primary group, a significant increase in the total number of leukocytes, lymphocytes, and T-lymphocytes in the blood was noted, as well as an improvement in the functional activity of T-cells (Table 4). These changes correlated with the positive dynamics of the subjective state, expressed in improved appetite, sleep, increased muscle tone, and decreased feelings of apathy.
As a result of the study, it was shown that ENDOLUTEN® is advisable to use in cancer patients after courses of radiation and chemotherapy to improve the general condition, maintain hematological and immunological parameters in the peripheral blood at the optimal level, and prevent the development of infectious complications.
When ENDOLUTEN® was included in the complex treatment regimens for various diseases associated with impaired neuroendocrine regulation, no side effects, complications, or drug dependence were identified.
Thus, the results obtained indicate the therapeutic and prophylactic efficacy of ENDOLUTEN® and the practicality of its use for prevention and in the complex treatment of various pathological conditions and diseases associated with impaired neuroendocrine regulation of the main functions of the body.

CONCLUSION

The biologically active food supplement ENDOLUTEN® has a normalizing effect on metabolism in the neuroendocrine system cells, particularly the pineal gland (pineal gland), and helps restore the neuroendocrine regulation of the body's main functions.
ENDOLUTEN® is well tolerated when taken orally, has no side effects, and can be widely used as a therapeutic and prophylactic biologically active food supplement.
ENDOLUTEN® is recommended for use:
- To patients with dyshormonal myocardial dystrophy - orally 10-15 minutes before meals, 1-3 capsules 2-3 times a day for 15-30 days, depending on the severity of the pathological process;

- To patients with mild and moderate climacteric syndrome - orally 10-15 minutes before meals, 1-2 capsules 2-3 times a day for 30-60 days, depending on the severity of the pathological process;
- To patients with physiogenic asthenia - orally 10-15 minutes before meals, 1-3 capsules 2-3 times a day for 15-30 days, depending on the severity of the pathological process;
- To cancer patients after radiation or chemotherapy - orally 10-15 minutes before meals, 1-3 capsules 2-3 times a day for 30 days, depending on the severity of the pathological process;
- For prophylactic purposes in people whose professional activities are associated with psychoemotional, increased physical and emotional stress - orally 10-15 minutes before meals, 1 capsule 2 times a day for 15-30 days.

It is recommended to repeat a second course of treatment after 3-6 months.
It is advisable to recommend ENDOLUTEN®for therapeutic and prophylactic use and industrial production.

REFERENCES

1. Karpov R.S., Slepushkin V.D., Mordovin V.F., KhavinsonV.Kh., Morozov V.G., Grishchenko V.I. - The use of pineal gland preparations in clinical practice. - Tomsk: Publishing house of Vol. University, 1985. -- 152 p.
2. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
3. Novikov V.S., Smirnov V.S. Immune physiology of extreme conditions. – SPb.: Nauka, 1995. – 172 p.
4. Pierpaoli V., Regelson W. The Miracle of Melatonin: Per. from English - M.: Eastern Book Company, 1997. -- 256 p.
5. Slepushkin V.D., Anisimov V.N., KhavinsonV.Kh., Morozov V.G., Vasiliev N.V., Kosykh V.A. - Epiphysis, immunity and cancer. - Tomsk: Publishing house of Vol. University, 1990. -- 148 p.
6. Tepperman J., Tepperman H. Physiology of metabolism and the endocrine system: Translation from English - M.: Mir, 1989. -- 656 p.

RECOMMENDATIONS FOR USE

ENDOLUTEN® is a complex of peptides obtained from the pineal gland (pineal gland) tissues of young animals. The isolated peptides have a selective effect on the neuroendocrine cells of the pineal gland, normalize metabolism in cells, and regulate their functions.
In the clinical study, the effectiveness of ENDOLUTEN® was established for the prevention and complex treatment of diseases and pathological conditions associated with impaired neuroendocrine regulation (climacteric syndrome, physiogenic asthenia, desynchronosis) when the body is exposed to extreme environmental factors, including occupational factors and psychoemotional stress, as well as aging.
Take 1-2 capsules or tablets of ENDOLUTEN® 1-3 times a day with meals. The duration of admission is 30 days. It is advisable to repeat the course in 4-6 months.
Do not use in case of: individual intolerance to the components, pregnancy, or breastfeeding.
There were no side effects identified when using ENDOLUTEN®.
Store in a dry, dark place at a temperature from +2 to +25 °C.
Release form: 20 capsules or tablets containing 10 mg of ENDOLUTEN®.
Expiration date: 5 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

6 geroprotectors

CYTOGENES

Cytogens are synthesized from natural amino acids, resulting in a copy of the working part of the most active part of the peptide from the entire complex contained in the extract, that is, one shortened molecule. Synthesized peptides have a faster effect, in the beginning, starting up the function of restoring internal organs. In the future, to continue the positive dynamics in therapy, it is recommended to take Cytomaxes.
Physiologically active short peptides should be used at any age to maintain a normal level of metabolic processes, prevent various diseases, and slow down the aging process in the body.

St. Petersburg

Vesugen®

Report on the results of clinical studies of the biologically active food supplement **Vesugen®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement VESUGEN® is a peptide complex containing amino acids: lysine, glutamic acid, aspartic acid, which has a normalizing effect on vascular tissue.
VESUGEN® is available in tablets or capsules with an active substance content of 0.100 mg.
Experimental studies have shown that VESUGEN® has a tissue-specific effect on the cells of the tissues of the vascular wall, improves their trophism, and provides regulating action on the metabolic processes in them. It contributes to the normalization of functional and morphological changes in the vascular wall, regulates cholesterol and lipoproteins blood content, reducing the risk of various vascular defects. Thus, it is possible to extrapolate the efficiency of the use of VESUGEN® for the restoration of vascular function in multiple diseases, including atherosclerosis.
Atherosclerosis and its consequences are one of the leading causes of disability among the population and death in developed countries. Age-related changes in the vascular wall and hemodynamic disturbances lead to decreased peripheral blood circulation, vascularization of organs and tissues, the development of various components of oxygen deficiency, and trophic disorders in various organs and tissues (2, 3, 4, 6). Drug treatment of atherosclerosis aims to normalize lipid metabolism, blood coagulation, and metabolism in the vascular wall (1, 5).
Medicines that normalize cholesterol and β-lipoprotein levels:
- Drugs, which prevent the absorption of cholesterol in the intestine (cholestyramine, β-sitosterol, diosponin, polysponine);
- Drugs, which affect cholesterol synthesis in the body (clofibrate, miscleron, regardin, cetamifen, nicotinic acid, vitamin PP);
- Drugs, which enhance the disintegration and excretion of cholesterol from the body (linetol, arachiden).
Means that improve microcirculation, normalize vascular permeability, reduce swelling of vascular tissues and improve metabolic processes in the vascular wall:
- prodectin, dicynon, doxium, glivenol, escuzane, etc.
Clinical trials of VESUGEN® took place at the Medical Center of the Saint Petersburg Institute of Bioregulation and Gerontology of the Northwest Branch of the Russian Academy of Medical Sciences in patients with atherosclerosis of various arteries in the period from November 2005 to February 2006.

Distribution of patients by nosological forms, sex and age

Table 1

Diagnosis	Age (Years)	Men		Women		Total	
			Primary group	Control group	Primary group	Control group	Primary group
Atherosclerosis	54-77	8	15	7	10	15	25
Total:						40	

CLINICAL CHARACTERISTICS OF PATIENTS

40 patients with atherosclerosis participated in the clinical trials, 25 of whom made up the primary group (15 men, 10 women). In addition to conventional drugs, they were prescribed VESUGEN® orally 10-15 minutes before meals, 1-2 capsules 2-3 times a day for 10-15 days, depending on the severity of the pathological process. 15 patients (8 men, 7 women) included in the control group were prescribed only conventional drugs. The age of patients in both groups ranged from 54 to 77 years (Table 1).
Patients in both groups had different clinical manifestations of atherosclerosis, depending on vascular lesions of different calibers: hypertension, coronary heart disease, cerebrovascular disorders with impaired memory, concentration, and affective lability. All patients showed progressive dynamics of disease development.
All patients previously received symptomatic and pathogenic therapy for specific clinical signs of vascular pathology.

RESEARCH METHODS

The patients' complaints were assessed and compared, a general clinical examination of blood and urine was carried out alongside a biochemical study of blood using the «REFLOTRON» device (Boehringer Mannheim, Germany). A blood coagulogram and tourniquet Hesse testing were carried out to assess homeostasis.

RESEARCH RESULTS

The use of VESUGEN® in patients with arterial atherosclerosis contributed to the improvement of general health, normalization of sleep, especially in patients with cerebrovascular disorders. Patients with ischemic heart disease noted a decrease in cardiac arrhythmias manifestations and angina attacks.

Patients with essential hypertension associated the normalization of blood pressure with the use of VESUGEN® in combination with antihypertensive drugs since it was possible to achieve long-term remission between hypertensive crises with a lower dose of conventional antihypertensive drugs.

As we can see from table 2, the use of VESUGEN® contributed to a significant decrease in the level of total cholesterol in the blood. There was also a tendency to decrease the content of very-low-density lipoproteins, which are the most atherogenic.

Table 2

Influence of VESUGEN®on lipid metabolism indicators in patients with arterial atherosclerosis

Indicator	Before treatment	After treatment using general purpose drugs	After treatment using Vesugen®
General cholesterol, (mmol/l)	8,2±0,3	7,0±0,2*	6,4±0,3*
Very little density lipoproteins, (mmol/l)	1,23±0,05	1,08±0,04	0,96±0,05
Triglycerides, (mmol/l)	4,5±0,2	4,2±0,7	4,1±0,2

*P<0,05–reliable in comparison with the indicator before treatment.

Thus, the results of this study indicate the therapeutic efficacy of VESUGEN® and the advisability of its use in the complex treatment of atherosclerosis and vascular pathology.

VESUGEN® administration has not resulted in any side effects, complications, contraindications, or drug dependence.

VESUGEN® is convenient for administration in hospitals, outpatient, and home use.

VESUGEN® can be used for therapeutic and prophylactic purposes as a biologically active food supplement as part of the complex therapy of vascular atherosclerosis and improve microcirculation in various tissues in combination with any means of symptomatic and pathogenetic treatment.

CONCLUSION

The biologically active food supplement VESUGEN® has a regulatory effect on metabolism in the vascular wall cells, contributing to the regulation of lipid metabolism and improving the state of the vascular wall.

VESUGEN® is well tolerated at oral administration, has no side effects, has no contraindications, and can be used as part of the complex treatment and prevention of vascular diseases of various origins.

VESUGEN® is recommended to improve the functions of the vascular wall in cases of atherosclerosis, microcirculation disorders in organs and tissues in various diseases, and the influence of various extreme factors on the body. It is also recommended for the elderly to maintain vascular system function.

Recommended dosages: orally 10-15 minutes before meals, 1-3 tablets or capsules 2-3 times a day for 10-20 days. It is advisable to carry out repeated courses of treatment every 3-6 months.

REFERENCES

1. Belousov Y.B., Moiseev V.S., Lepakhin V.K. Clinical Pharmacology and Pharmacotherapy: A Guide for Physicians. - M .: the Universe, 1993 .-- 398 p.
2. Blood disorders in the elderly: Translation from English / Ed. M.J. Denham, I. Chanarin. - M.: Medicine, 1989 .-- 352 p.
3. Hormones and vascular diseases: Translation from English / Ed. R.M. Greenhalga. - M.: Medicine, 1984 .-- 344 p.
4. Korkushko O.V. Cardiovascular system and age. – M.: Medicine, 1983. – 176 p.
5. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
6. Geriatry manual / Ed. D.F. Chebotarev, N.B. Mankovsky. – M.: Medicine, 1982. – 544 p.

RECOMMENDATIONS FOR USE

VESUGEN® is effective in correcting pathological changes occurring in vessels in various diseases.
VESUGEN® is well tolerated by patients, and no side effects, complications, contraindications, or drug dependence have been identified.
Adults are recommended to take 1-2 capsules 1-2 times a day with meals. The duration of admission is 10-30 days. It is advisable to repeat the course in 4-6 months.
Expiration Date: 5 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Cartalax®

Report on the results of clinical studies of the biologically active food supplement **Cartalax®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement CARTALAX® is a peptide complex containing amino acids: alanine, glutamic acid, aspartic acid, which has a normalizing effect on the cells of the immune system.
CARTALAX® is available in tablets or capsules with an active substance content of 0.100 mg.
Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. They improve the trophism of cartilaginous tissue cells and regulate metabolic processes in them, reducing the risk of various joint and spine diseases. Thus, it is possible to extrapolate the efficiency of CARTALAX® in restoring cartilaginous tissue function in patients with inflammatory and dystrophic-degenerative diseases of the musculoskeletal system.
Clinical trials of CARTALAX® took place at the Medical Center of the Saint Petersburg Institute of Bioregulation and Gerontology of the Northwest Branch of the Russian Academy of Medical Sciences in patients with osteoarthritis of joints, osteochondrosis of the spine, and osteoporosis during the period from October 2005 to February 2006.
CARTALAX® was administered to patients orally 10-15 minutes before meals, 1-3 tablets 2-3 times a day for 30-45 days, depending on the severity of the pathological process.
The treatment and rehabilitation of patients with degenerative-dystrophic diseases of the joints and spine, occurring with irreversible, progressive changes, is a complex problem that is most urgent in geriatric practice (2, 3).
Drug therapy for degenerative-dystrophic diseases of the joints and spine includes the use of various drugs of symptomatic and pathogenic action (1):
- Analgesics and anti-inflammatory drugs (analgin, novocaine blockade, rheopyrin, indomethacin, brufen);
- Antihistamines (diphenhydramine, pipolfen);
- Drugs, which improve peripheral blood circulation (pachikarpin, platifillin);
- Biostimulants (rumalon, aloe, vitreous body, ATP);
- Enzyme medication (lidase, ronidase);
- Anabolic steroids (neurabol, retabolil);
- etc.

CLINICAL CHARACTERISTICS OF PATIENTS

Thirty-three patients diagnosed with osteoarthritis, osteochondrosis, or osteoporosis participated in the clinical trials of CARTALAX®. Ten patients with osteoarthritis of the knee joints (7 men, 3 women), 15 patients with osteochondrosis of the spine (6 men, 9 women), and 8 patients with osteoporosis (8 women). The patients' age ranged from 45 to 78 years.
The control group included 31 patients with similar diagnoses, gender, and age. You can see the distribution of patients by diagnosis, sex, and age in Table 1.
Patients with osteoarthritis of the knee joints complained of pain and limitation of flexion and extension in the joints when walking. Representatives of the senior age group suffered from deformity of the joints, atrophy of the femoral muscles, and weakening of the ligamentous apparatus of the joints.
Patients in the second group often noted the pain in the lower back with irradiation along the sciatic nerve, significantly increasing with a change in body position, walking, and physical activity.
Osteoporotic patients complained of frequent bone fractures arising from minor trauma or even for no apparent reason.
In patients of the primary and control groups, the duration of the disease ranged from 5 to 20 years. A progressive dynamic of the development of the pathological process was noted.
All patients previously received analgesics and anti-inflammatory drugs for a long time, the use of which resulted in a short-term therapeutic effect, requiring an increase in the dose of drugs for the course of treatment and their prolonged use.
Patients in the control group received treatment using conventional drugs. In addition to traditional medicines, patients of the primary group have been taking CARTALAX® 2-3 capsules 2-3 times a day before meals for 30-45 days.

Distribution of patients by diagnosis, sex and age

Table 1

Diagnosis	Age (years)	Men		Women		Total	
		Control group	Primary group	Control group	Primary group	Control group	Primary group
Osteoarthritis of the knee joints	59-78	6	7	3	3	9	10
Osteochondrosis of the spine	45-69	7	6	8	9	15	15
Osteoporosis	45-65	-	-	7	8	7	8
Total:		13	13	11	12	31	33

RESEARCH METHODS

CARTALAX® efficiency assessment was carried out by analyzing the patient complaints progression and the objective parameters: general clinical analysis of blood and urine, biochemical blood analysis, X-ray examination.

RESEARCH RESULTS

It is important to note that radiology symptoms of degenerate and dystrophic diseases of joints and spine are objective diagnostic criteria of pathological process development stage and are of high prognostic importance for the drug therapy carried out.

The use of CARTALAX® in patients with knee joint osteoarthritis contributed to decreased pain syndrome and increased joint mobility in 68.5% of cases. At the same time, pain symptoms stopped mostly in radiologically identifiable initial stages of the disease: joint space narrowing between patella and femur, lateral osteophytes of the patella and femoral condyle. There were no considerable dynamics of roentgenological symptoms during this period.

In patients in the advanced stage of arthrosis, a similar but less pronounced dynamic of subjective indicators was observed. Such subjective sensations were very favorable since this stage of the disease was diagnosed in patients of the senior age group.

In patients with osteochondrosis of the lumbar spine, using CARTALAX® against the background of complex therapy helped reduce pain in 53.7% of cases. In these cases, long-term (at least 45-60 days) use of CARTALAX® smoothed the pain symptoms arising from pressure on the spine and lower extremities and increased the spine's mobility. Such changes were most typical for middle-aged people. Age-related disease progression, accompanied by typical radiological symptoms (narrowing of the space between adjacent vertebral bodies due to flattening degenerate intervertebral disks; anterior and posterior osteophytes of the vertebral bodies, arthritic changes of posterior and lateral intervertebral joints in the form of narrowing of the spaces, irregularity of the contours, osteophytes at the margins of the joint ends, and changes of the configuration of intervertebral foramens), resulted in the development of spondylosis and spondyloarthrosis, and the formation of neurodystrophic and neurovascular syndromes.

After long-term administration of the drug, the patients with osteoporosis have shown stabilization of metabolic processes in the bone tissue: reduction in the number of typical fractures, considerable acceleration of restoration of the function of the musculoskeletal system, and decrease in the time of stay in the hospital.

All patients showed a significant improvement in the main symptoms of their diseases.

CARTALAX® does not cause side effects, complications, or drug dependence.

Thus the results of the study carried out prove the efficiency of CARTALAX® and practicality of its use for complex treatment and prevention of degenerate and dystrophic diseases of the joints and vertebral

column combined with any means of symptomatic and pathogenic therapy used for the treatment of this group of diseases (analgesics, anti-inflammatory, antihistamine and vascular preparations, bio-stimulators, enzyme preparations, anabolic steroids, vitamins, etc.).

CONCLUSION

Biologically active food supplement CARTALAX® promotes the normalization of metabolic processes in cartilaginous tissue and slows down its involutive changes.
CARTALAX® can be used for therapeutic and preventative purposes in the form of a biologically active food supplement combined with any means of symptomatic and pathogenetic therapy used to treat degenerative-dystrophic diseases of the joints and spine (osteoarthritis, osteochondrosis, osteoporosis, etc.)
CARTALAX® is well tolerated by patients when taken orally, has no side effects, and can be widely used as a therapeutic and prophylactic biologically active food supplement.
CARTALAX® is recommended for:
- People with osteoarthritis of the joints - orally 10-15 minutes before meals, 2 tablets or capsules 3 times a day for 45 days;
- People with osteochondrosis of the spine - orally 10-15 minutes before meals, 2 tablets or capsules 3 times a day for 45 days;
- Peoplewith osteoporosis - orally 2 tablets or capsules 2 times a day 10-15 minutes before meals for 30 days.
It is recommended to repeat the course of treatment in 3-6 months.
It is advisable to recommend CARTALAX® for therapeutic and prophylactic use and industrial production.

REFERENCES

1. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
2. V.A. Nasonova, M.G. Astapenko Clinical Rheumatology: A Guide for Physicians. - M .: Medicine, 1989 .-- 592 p.
3. Geriatric manual / Ed. D.F. Chebotarev, N.B. Mankovsky. – M.: Medicine, 1982. – 544 p.

RECOMMENDATIONS FOR USE

Cartalax® was developed to correct and prevent connective tissue disorders that occur in various diseases. It is effective after extreme physical activity and to prevent degenerative processes in the spine and joints in elderly and senile people.
Cartalax® is well tolerated by patients, and there were no side effects, complications, contraindications, or drug dependence observed.
Adults are advised to take 1-2 capsules 1-2 times daily with meals. The duration of admission is 10-30 days. It is advisable to repeat the course in 4-6 months.
Expiration date: 5 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Crystagen®

Report on the results of clinical studies of the biologically active food supplement **Crystagen®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement CRYSTAGEN® is a peptide complex containing amino acids: glutamic acid, aspartic acid, and proline, which has a normalizing effect on the cells of the immune system. CRYSTAGEN® is available in tablets or capsules with an active substance content of 0.100 mg.
CRYSTAGEN® regulates metabolic processes in the cells of the immune system, restores impaired immunological reactivity, and stimulates regeneration processes in case of their suppression. Experimental studies have shown that peptides have a tissue-specific effect on the cells of those tissues from which they are isolated. Thus, it is possible to extrapolate the efficiency of KRYSTAGEN® to restore the function of the immune system in various pyoinflammatory and other diseases characterized by the suppression of the immune status of patients.
It is known that various factors of physical, chemical, and biological nature, depending on the duration and intensity of their impact on the human body, can lead to depletion of adaptive and compensatory mechanisms and cause profound disorders of various segments of the immune defense system (2, 3). Pathological disorders in the immune system usually result in a long-term course of the basic disease with a tendency to relapse, a decrease in the body's resistance to infection, and the development of severe complications.
Among the drugs that contribute to the restoration of immunological reactivity are immunomodulators of various origins: enzyme medication (trypsin, lysozyme), bacterial polysaccharides (pyrogenal, prodigiosan), yeast polysaccharides (zymosan, glucans, propermil, dextrans), vaccines (BCG), nucleic acid medication (sodium nucleinate), purine and pyrimidine derivatives, levamisole, diucifon, traditional medicine, and many others (1, 2).
Clinical trials of CRYSTAGEN® were carried out in the period from November 2005 to February 2006 at the Medical Center of the Saint Petersburg Institute of Bioregulation and Gerontology of the Northwest Branch of the Russian Academy of Medical Sciences, in patients after long-term exposure to low doses of ionizing radiation, including cancer patients after radiation and chemotherapy.
The primary group consisted of 40 patients (23 men, 17 women), who, in addition to conventional treatments, were prescribed CRYSTAGEN® 1-3 capsules 2-3 times a day before meals for 15-20 days, depending on the severity of immune status disorders. Patients in the control group received only general-purpose medication.
The age of patients in both groups ranged from 38 to 69 years. The distribution of patients by nosological forms, sex, and age is presented in Table 1.

Distribution of patients by nosological forms, sex and age. Table 1

Diagnosis	Age (years)	Men		Women		Total	
		Control group	Primary group	Control group	Primary group	Control group	Primary group
State after low-dose ionizing radiation influence	38-56	10	14	5	6	15	20
State after radiation and chemotherapy in oncological patients	43-69	8	9	7	11	15	20
Total		18	23	12	17	30	40

RESEARCH RESULTS

CRYSTAGEN® efficiency was assessed by changes of the patients' complaints and by the number of objective parameters: General clinical analysis of blood and urine, the immunological study of peripheral blood (the number of T- and B-lymphocytes was determined by the immunofluorescence method with monoclonal antibodies to differentiation lymphocyte antigens CD3, CD4, CD8, CD20; the content of immunoglobulins of various classes - by the method of radial immunodiffusion in gel according to Mancini; functional activity of T-lymphocytes - using leukocyte migration inhibition test

(LMIT) with ConA).
Studies have shown that 90% of people living in an ecologically unfavorable area have immune status disorders in the form of a decrease in the number of CD3+, CD4+ cells, with a slight increase in lymphocytes with the CD8+ phenotype, which indicates a decrease in the level of immunoreactivity (CD4+/CD8+). The results of LMIT with ConA characterize a decrease in the functional activity of T-lymphocytes (mainly CD8+, i.e., T-suppressors/killers). The number of CD20+ -cells, representing a subpopulation of B-lymphocytes, was not significantly different from normal values, but, at the same time, there was an increase in the number of M and G immunoglobulins in blood serum (Table 2).
It should be noted that the quantitative indicators of the content of CD3+ and CD4+ cells are typical for lower limits of physiological fluctuations in their number in patients of such age, which may indicate premature aging of the immune system. As a rule, people with a secondary immune-deficiency condition have a pronounced asthenic syndrome and significant changes in the cardiovascular system.

CRYSTAGEN® **influence of the cellular and humoral immunity parameters in patients, who have been exposed to low doses of ionizing radiation**

Table 2

Parameter	Before treatment	After treatment with general purpose medication	After treatment using Crystagen®
Leucocytes, ×10⁹/l	5,1±	5,2±0,5	5,4±0,3
Lymphocytes, % **×10⁹/l**	28,1±2,2 1,62±0,03	29,7±2,1 1,56±0,06	32,1±1,8 1,67±0,04
CD3⁺, % **×10⁹/l**	45,1±2,1 1,50±0,03	49,3±2,3 1,61±0,02	53,3±2,2* 1,77±0,03*
CD4⁺, % **×10⁹/l**	26,3±2,4 0,44±0,02	29,7±2,4 0,47±0,04	32,1±1,8* 0,56±0,05*
CD8⁺, % **×10⁹/l**	26,4±1,5 0,43±0,05	25,7±1,6 0,42±0,03	24,9±1,8 0,46±0,07
CD4⁺/CD8⁺	1,0	1,1	1,2
CD20⁺, % **×10⁹/l**	12,2±0,5 0,20±0,02	12,1±0,2 0,22±0,01	12,2±0,6 0,21±0,01
Leukocytemigrationinhibitiontest, %	86,3±4,7	74,7±4,2*	71,9±4,4*
IgM, (g/l)	1,76±0,03	1,69±0,06	1,74±0,02
IgG, (g/l)	15,1±1,2	15,4±1,4	15,2±1,5
IgA, (g/l)	2,0±0,2	2,1±0,1	2,1±0,2

* P<0,05 – significantly compared to the indicator before treatment.

The results of the studies conducted convincingly indicate that CRYSTAGEN® is an effective remedy for correcting secondary immune deficiency that develops in response to the influence of extreme factors. The use of KRYSTAGEN® in combination with symptomatic agents made it possible to normalize the impaired parameters of the immune system in 78% of cases.
According to the data provided, the greatest effect from the use of CRYSTAGEN® was identified in subpopulations of T-lymphocytes and their functional activity (a significant increase in the number of CD3+ and CD4+ lymphocytes, normalization of the CD4 /CD8+ ratio). A less distinct reaction was noticed in the B-system, probably, due to its higher conservativity.
After the course of treatment using CRYSTAGEN®, patients who received small doses of ionizing radiation noted a significant improvement in their general condition and a decrease in the severity of the asthenic syndrome, which always accompanies secondary immunodeficiencies.

Oncological patients after radiation and chemotherapy had increased normalization of immunological indices compared to the control group, which resulted in improvement of their general condition and a decrease in the rate of complications. It is noteworthy that the primary group patients tolerated radiation and chemotherapy better and were able to complete the entire course of treatment (in the control group - 79%).

CONCLUSION

Clinical trials have shown that CRYSTAGEN® promotes normalization of cellular immunity parameters, stimulates tissue regeneration processes in case of inhibition, and does not result in any side effects, complications, or drug dependence. It can be used for treatment and prophylactic purposes combined with any means of symptomatic and pathogenetic therapy used to correct secondary immunodeficiency conditions (immune modulators, adaptogens, vitamins, etc.).
CRYSTAGEN® is recommended for accelerating the restoration of the immune system functions after infectious diseases, radiation, and chemotherapy, influence on the body of various extreme factors (including ionizing and UHF-radiation). It is also recommended for elderly people to maintain immune system function.
It is recommended to take CRYSTAGEN® 10-15 minutes before meals, 1-3 tablets or capsules 2-3 times a day for 20-30 days.
A second course is recommended in 3-6 months.
The clinical study showed no side effects, complications, contraindications, or drug dependence when using CRYSTAGEN®.

REFERENCES

1. Drannik G.N., Grinevich Y.A., Disik G.M. Immunotropicmedication. – Kiev Zdorov'ya, 1994. – 288 p.
2. Mashkovsky M.D. Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO "Gamta", 1993.
3. Novikov V.S., Smirnov V.S. Immune physiology of extreme conditions. – SPb.: Nauka, 1995. – 172 p.
4. Schek M.G., Kosinets A.N., Adamenko G.P. Immunological aspects of surgical infection. – Vitebsk: B. i., 1994. – 140 p.

RECOMMENDATIONS FOR USE

CRYSTAGEN® was developed to correct the immune system and prevent hormonogenesis disorders that occur in various diseases. It is effective for maintaining the function of the immune system in elderly and senile people, in case of chronic intoxication, as well as for rejuvenating the body as part of complex programs. CRYSTAGEN® is well tolerated by patients, and there were no side effects, complications, contraindications, or drug dependence observed.
Adults are advised to take 1-2 capsules 1-2 times daily with meals. The duration of admission is 10-30 days. It is advisable to repeat the course in 4-6 months.
Expiration date: 5 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Ovagen®

Report on the results of clinical studies of the biologically active food supplement **Ovagen®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement OVAGEN® is a peptide complex containing amino acids: glutamic acid, aspartic acid, and leucine, which has a normalizing effect on liver cells.
OVAGEN® is available in tablets or capsules with an active substance content of 0.100 mg.
Clinical trials of OVAGEN® were carried out at the Medical Center of the Saint Petersburg Institute of Bioregulation and Gerontology of the Northwest Branch of the Russian Academy of Medical Sciences in patients with chronic hepatitis and oncological patients after a course of radiation or chemotherapy in the period from October 2005 to February 2006.
OVAGEN® was administered to patients orally 10-15 minutes before meals, 1-2 tablets 2 times a day for 10-20 days, depending on the severity of the pathological process.
Currently, there is an increase in the number of patients with chronic liver diseases, which are prevalent mainly in people of working age. Unfavorable social and environmental factors mainly cause them. Chronic hepatitis is not considered an outcome of an acute infectious process but as a form of the course of the infectious process (2, 3).
In the treatment of patients with chronic hepatitis, taking into account the pathogenetic mechanisms, the following conventional therapeutic agents are used (1):
- Drugs that improve the metabolism of liver cells (hepatoprotectors) – (Essentiale, Legalon, Sirepar);
- Stimulants of bile secretion – (Liv-52);
- B group vitamins (B1, B6, B12, ascorbic acid);
- etc.

CLINICAL CHARACTERISTICS OF PATIENTS

Clinical trials were carried out in 40 patients with chronic hepatitis and oncological patients after a course of chemotherapy, including 25 men and 15 women from 38 to 67 years old (Table 1). In addition to conventional treatment, patients of the primary group received OVAGEN® - 2 capsules 2 times a day before meals for 15-20 days. The duration of their disease ranged from 3 to 10 years.
The control group consisted of 34 similar patients who were prescribed only conventional medication.

Distribution of patients by nosological forms, sex and age. Table 1

Diagnosis	Age (years)	Men	Women	Total
Chronic persisting hepatitis	38-67	14	6	20
State after chemotherapy course in oncological patients	50-65	11	9	20
Total:		25	15	40

Most patients complained about pain in the right hypochondrium, general weakness, and rapid fatigability. 78% of patients had dyspeptic disorders. 55% of patients had hyperbilirubinemia, an increase in the alanine aminotransferase level, and an increase in the globulin fraction of blood proteins, mainly due to the M immunoglobulin fraction, which indicates a specific activity of the chronic inflammatory process.

RESEARCH METHODS

The complaints were assessed subjectively at different times. The following tests were carried out: general clinical examination of blood and urine, biochemical and immunological blood tests (determination of immunoglobulins using the Mancini method), and liver ultrasound examination.

RESEARCH RESULTS

After treatment with OVAGEN®, most patients noted a significant increase in energy, appetite, and

performance. 48% of patients noticed a considerable decrease in the intensity of the pain syndrome. Cancer patients noted an improvement in their well-being, a decrease in weakness, and the intensity of dyspeptic disorders.

Influence of OVAGEN® on Biochemical indicators of peripheral blood in patients with chronic hepatitis.

Table 2

Indicator	Before treatment	After Treatment with Conventional Means	After Treatment with Ovagen®
Cholesterol, (mmol/l)	4,8±0,3	4,9±0,1	4,7±0,6
Bilirubin, (mcmol/l)	28,4±0,5	26,4±1,1	21,5±0,7*
AST, (mmol/hxl)	38,6±2,1	40,2±2,2	36,1±2,5
ALT, (mmol/hxl)	50,2±3,2	44,3±3,1*	41,4±2,8*
g-GT, (mmol/hxl)	44,7±4,3	42,6±4,0	41,4±4,1
Triglycerides, (mmol/l)	2,2±0,2	2,1±0,7	1,8±0,4

* P <0.05 - reliablein comparison with the parameter before treatment.

When analyzing the effectiveness of OVAGEN®, particular attention was paid to assessing the results of biochemical studies characterizing the liver's aminotransferase activity, pigment, and protein-forming functions. Objectively, after using OVAGEN®, biochemical parameters were stabilizing in most patients: bilirubin level, alanine aminotransferase level (Table 2). The study of peripheral blood immunoglobulins, which are an essential criterion for the inflammatory process activity, after a course of treatment using OVAGEN® showed a decrease in IgM level (Table 3).
Thus, the results of clinical trials indicate the hepatoprotective properties of OVAGEN® and the advisability of its use in the complex treatment of acute and chronic forms of liver damage in cancer patients after radiation and chemotherapy as for the prevention of various liver diseases and their complications.
During clinical trials of OVAGEN®, there were no side effects, contraindications, complications, or drug dependence.

Influence of OVAGEN® on immunological parameters of patients with chronic hepatitis

Table 3

Parameters	Before treatment	After treatment with general purpose drugs	After treatment using Ovagen®
IgA, (g/l)	2,2±0,08	2,2±0,02	2,3±0,08
IgM, (g/l)	3,6±0,03	2,5±0,08*	2,1±0,03*
IgG, (g/l)	14,0±1,2	14,2±1,0	14,1±1,1

* P <0.05 - reliable in comparison with the parameter before treatment.

REFERENCES

1. Mashkovsky M.D. Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.
2. Podymova S.D. Liver diseases. – M.: Medicine, 1984. – 480 p.
3. Rakhmanova A.G., Prigozhina V.K., Neverov V.A. Infectious diseases: Manual for general practitioners. – M.-SPb.: Pub. “SSZ”, 1995. – 304 p.

RECOMMENDATIONS FOR USE

OVAGEN® is recommended for the acceleration of the recovery of liver function in acute or chronic liver damage, in treatment using antibiotics and other drugs that adversely affect the liver, malnutrition, for cancer patients after radiation or chemotherapy and when the body is exposed to various extreme factors. In addition, the drug is recommended for the elderly to maintain liver function.
OVAGEN® is recommended to be taken 10-15 minutes before meals, 1-2 tablets or capsules 2-3 times a day for 15-20 days.
A second course could be repeated in 3 - 6 months.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Pinealon®

Report on the results of clinical studies of the biologically active food supplement **Pinealon®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement PINEALON® is a peptide complex containing amino acids: glutamic acid, aspartic acid, and arginine, which has a normalizing effect on brain tissue.
PINEALON® is available in tablets or capsules with an active substance content of 0.100 mg.
Experimental studies have shown that PINEALON® has a tissue-specific effect on brain cells: it regulates metabolic processes in brain cells, increases the reserve capacity of the brain, exerts a beneficial impact on the body's adaptation processes in extreme conditions, has antioxidant properties, and regulates the processes of peroxidation in the cerebral cortex of the brain. This allows us to assume the effectiveness of using PINEALON® to restore the functions of the central nervous system in the case of disorders of various origins.
Treatment of central nervous system diseases is of particular relevance because they lead to social adaptation disorder and disability of patients (2).
Currently, the treatment of patients with diseases of the central nervous system, given the pathogenetic mechanisms, is carried out using the following traditional therapeutic agents of various action types (1, 3):
- Influence on metabolism and integrative functions of the brain – (cerebrolysin, piracetam, encephalolysate);
- Normalization of cerebral and systemic circulation – (stugeron, cavinton);
- Relief of psychopathological symptoms – (meridin, amitriptyline);
- Correction of changes in the bioelectric activity of the brain – (phenobarbital, Convulex);
- Impact on liquorodynamic disturbances – (verospiron, furosemide);
- Prevention and inhibition of the development of adhesions – (aloe, lidase);
- Correction of immunopathological reactions – (levamisole, tavegil).

Clinical trials of PINEALON® took place from November 2005 to February 2006 at the Medical Center of the Saint Petersburg Institute of Bioregulation and Gerontology of the Northwest Branch of the Russian Academy of Medical Sciences.
In total, 42 patients with various diseases of the central nervous system participated: long-term consequences of craniocerebral injury (the duration of the injuries varied between 1 to 10 years), post-stroke conditions, vascular encephalopathies, decreased mental performance, memory, attention. You can see the distribution of patients by nosological forms, sex, and age in Table 1.
In addition to conventional treatment, patients in the primary group received PINEALON® 1-2 capsules 2-3 times a day before meals for 10-20 days, depending on the severity of the pathological process.
The control group consisted of 32 similar patients who received only conventional treatment.
All patients have been taking symptomatic and pathogenetic drugs. Taking these drugs has resulted in a short-term therapeutic effect, which required an increase in the dose per treatment course and their prolonged use.

Distribution of the patients by nosological groups, sex and age.

Table 1

Diagnosis	Age (years)	Men		Women		Total	
		Control group	Main group	Control group	Main group	Control group	Main group
Long-term effects of craniocerebral injury	35-65	5	7	1	1	6	8
State after stroke	56-75	5	6	1	3	6	9
Vascular encephalopathies	55-78	5	7	5	8	10	15
Signs of decreased mental capacity, memory, attention.	51-68	6	5	4	5	10	10
Total:		21	25	11	17	32	42

RESEARCH METHODS

The effectiveness of PINEALON® was assessed by the dynamics of subjective indicators and objectively using the methods of proofreading and electroencephalography (EEG).

RESEARCH RESULTS

After administrating PINEALON® to patients of the primary group, a good clinical result was observed in 66.7% of cases, satisfactory - in 23.8%, no positive effect - in 9.5% of cases (in the control group - Table 2). There was no negative effect of PINEALON® on the condition of the patients.

PINEALON® efficiency in patients with diseases of the central nervous system

Table 2

Treatment results	Group of patients			
	Treatment using general purpose medication		Treatment using “Pinealon”	
	Abs.	%	Abs.	%
Good	9	28,1	28	66,7*
Satisfactory	13	40,6	10	23,8
Not satisfactory	10	31,2	4	9,5*
Total:	32	100	42	100

* P<0,05 in comparison with the parameters after treatment using general purpose drugs.

When comparing the subjective indicators of the state of patients before and after the use of PINEALON®, it was found that the number of health complaints decreased by 2-3 times. Patients noted an improvement in memory, intelligence, a decrease in the intensity and duration of headaches, the appearance of emotional balance, volitional qualities, and a sense of rest after a night’s sleep (Table 3). Patients with the consequences of craniocerebral injury and stroke noticed a moderate regression of focal symptoms, improved speech function with motor and sensory aphasia, and decreased muscle spasticity.

Comparative assessment of the effect of PINEALON® and other treatment methods on the integral function of the brain - attention and bioelectrical activity of the brain were studied using a corrective test and electroencephalography, respectively.

Table 3

Influence of PINEALON® on subjective indicators of the state of health of the patients.

Indicator	Before treatment, %	After treatment using general purpose drugs, %	After treatment using PINEALON®, %
Headaches	81,2	51,3#	36,4#
Sleep disturbances	52,6	39,2#	26,1#
Emotional instability	73,9	48,4#	27,2*#
Memory disturbance	57,2	48,1	34,2*#
Absent-mindedness	44,8	41,1	27,5*#
Rapid fatigability	78,3	50,7#	39,3*#

# P <0.05 compared with the indicator in patients before treatment;
* P <0.05 compared with the indicator in patients after treatment with general purpose drugs.

Influence of PINEALON® on the dynamics of indicators of performing a correction test by patients with diseases of the central nervous system

Table 4

Group of examined patients	Number of symbols viewed	Number of errors
Healthy	1760,8±75,1	8,26±1,9
Patients before treatment	1257,6±68,2	16,3±1,2
Patients after treatment with general purpose drugs	1611,3±61,2*	12,5±1,1*
Patients after treatment using Pinealon®	1669,1±56,3*#	9,1±0,8*#

* P <0.05 compared with the indicator in patients before treatment;
# P <0.05 compared with the indicator in patients after treatment with general purpose drugs.

You can observe the results of completing the correction task by the patients after treatment using various methods in table 4. According to the table, the patients after treatment using PINEALON® have a higher number of symbols viewed and fewer errors. The best results were obtained in the primary group patients when analyzing the dynamics of performing the correction test before and after treatment compared to patients in the control group. This was expressed in the absence of sharp fluctuations in the number of viewed symbols for equal periods, the presence of a period of «workability» by the middle of the task, and a gradual decrease in the curve by the end of the task, which indicates greater stability of attention after treatment.

To assess the effect of PINEALON® on the bioelectrical activity of the brain, a visual analysis of the EEG was performed by distributing them by type and the calculation of the alpha index before and after treatment. EEG was performed selectively on patients with the most pronounced manifestations

of pathological processes. The research results are presented in Table 5.

The influence of PINEALON® on the characteristics of the types of electroencephalograms in patients with diseases of the central nervous system. Table 5

Group of patients examined	EEG Type					
	III		IV		V	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
After treatment with general purpose drugs	6 (19%)	5 (16%)	11 (34%)	10 (31%)	10 (31%)	9 (28%)
After treatment using PINEALON®	9 (21%)	7 (17%)	14 (33%)	9 (21%)	13 (31%)	7 (17%)

Before treatment, pathological (III, IV, V) types of EEG prevailed in the examined patients in different groups. Type III EEG was characterized by the presence of a so-called non-dominant curve at a low amplitude level (no higher than 30-35 μV), the presence of irregular alpha activity, or even its absence. The IV type of EEG was characterized by a highly emphasized regularity of rhythms, blurring of zonal differences. The V type of EEG was characterized by irregular slow activity with an amplitude above 35 μV, sharp waves, and paroxysmal discharges.
The most pronounced changes in the brain's bioelectric activity were observed in patients after treatment with PINEALON®. First of all, this was confirmed on the EEG in a clearer modulation and restoration of zonal differences in the alpha rhythm, a weakening of the severity of irritative processes, in some cases - the disappearance of paroxysmal discharges.

Effect of PINEALON® on the dynamics of changes in the alpha index in patients with diseases of the central nervous system Table 6

Group of patients examined	Alpha index	
	Before treatment	After treatment
Healthy	51,7±3,2	-
Patients using general purpose drugs	36,2±3,4	43,2±4,5
Patients using Pinealon®	1669,1±56,3*#	46,1±4,5*#

* P <0.05 compared with the indicator in patients before treatment;
\# P <0.05 compared with the indicator in patients after treatment with general purpose drugs.

In addition to visual EEG assessment, the alpha index was calculated in patients before and after treatment (Table 6). It was found that there was a significant increase in the alpha index in patients of the study groups under the influence of therapy. The value of the alpha index was significantly higher in the group of patients after treatment with PINEALON® compared with the indicators in other groups. However, the degree of change in the alpha index in patients receiving different treatments was not the same.

CONCLUSION

Based on the data obtained, it is possible to conclude that the activation of reserve capacities of the cerebral cortex with the help of PINEALON® improves the integral functions of the brain.
Thus, the clinical study results indicate the effectiveness and practicality of using PINEALON® in the complex treatment and prevention of diseases of the central nervous system of various origins.
PINEALON® does not cause side effects, complications, or drug dependence; no contraindications have been identified during clinical trials.
PINEALON® can be used for therapeutic and prophylactic purposes, including in combination with any means of symptomatic therapy used in neurological practice (vascular, nootropic, absorbable, anticonvulsant, vitamins, etc.).

REFERENCES

1. Kovalev G.V. Nootropic medicines. – Volgograd: Nizh.-Volzh. publishing house, 1990. – 368 p.
2. Treatment of nervous diseases: Translated from English/ Edited by V.K.Viderholt. – M.: Medicine, 1984. – 560 p.
3. Mashkovsky M.D. Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO “Gamta”, 1993.

RECOMMENDATIONS FOR USE

PINEALON®is recommended to be used to accelerate the recovery of craniocerebral injuries, stroke, intellectual disorders, and exposure to various extreme factors. In addition,the medication is recommended for the elderly to maintain mental performance.
PINEALON®is recommended to be taken 10-15 minutes before meals, 1-3 tablets or capsules 2-3 times a day for 10-20 days.
It is desirable to repeat the course in 3 - 6 months.
There are no contraindications and side effects when using PINEALON®.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)

St. Petersburg

Chonluten®

Report on the results of clinical studies of the biologically active food supplement **Chonluten®**

«APPROVED» V.K. KHAVINSON
Director of the Medical Center St. Petersburg Institute of Bioregulation and Gerontology SZO RAMS, Corresponding Member of the Russian Academy of Medical Sciences, Professor, Doctor of Medical Sciences

2011

Biologically active food supplement CHONLUTEN® is a peptide complex containing amino acids: glutamic acid, aspartic acid, glycine, which has a normalizing effect on the cells of the bronchial mucosa. CHONLUTEN® is available in tablets or capsules with an active substance content of 0.100 mg.
The results of experimental studies have shown that CHONLUTEN® has a tissue-specific effect on the cells of the bronchial mucosa, improves their trophism and has a regulatory effect on metabolic processes in them, contributes to the normalization of functional and morphological changes in the bronchial mucosa, reducing the risk of various inflammatory diseases of the bronchi and lungs. This suggests the effectiveness of CHONLUTEN®'s use to restore the function of the respiratory system in various inflammatory diseases.
Chronic bronchitis is a severe medical and social problem due to its high prevalence, growing sickness rate, mortality, and enormous economic damage to society. Chronic bronchitis is the main form in the structure of chronic nonspecific lung diseases (3, 4).
Medical treatment of chronic bronchitis includes the use of the following drugs (1, 2):
- Antibiotics (penicillin, kanamycin, oleandomycin);
- Sulfonomides (biseptol, madribone);
- Bronchodilators (aminophylline, ephedrine, salbutamol, phentolamine);
- Expectorants (bromhexine, thermopsis);
- Immunomodulators (thymalin, taktivin);
- Glucocorticoids (hydrocortisone, prednisolone, dexamethasone), etc.

Clinical trials of CHONLUTEN®were carried out at the Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS in patients with chronic bronchitis with an asthmatic component in the period from November 2005 to February 2006.

CLINICAL CHARACTERISTICS OF PATIENTS

Treatment with CHONLUTEN® was carried out in 23 patients (15 men, 8 women) with a diagnosis of chronic bronchitis with an asthmatic component, remission phase. The patients' age ranged from 38 to 65 years.
Patients complained of coughing up phlegm, mainly in the morning, general weakness, sweating, shortness of breath during physical activity, recurrent attacks of suffocation, sleep disturbances, and headaches.
The duration of the course of the disease in patients was 3-10 years, and there were progressive dynamics of the development of the pathological process.
All patients previously received symptomatic and pathogenetic therapy for this disease.
The control group consisted of 19 patients with a similar disease who were prescribed traditional treatment.

RESEARCH METHODS

CHONLUTEN®'s efficiency assessment was carried out by analyzing the patients' complaints progression, general clinical examinations of blood and urine, and biochemical blood study using the REFLOTRON apparatus (Boehringer Mannheim, Germany). Additionally, radiography of the lungs, microscopic examination of sputum, and analysis of the function of external respiration were performed.

RESEARCH RESULTS

It was found that the use of CHONLUTEN® against the background of conventional therapy in patients with chronic bronchitis in 73% of cases contributed to an improvement in well-being, a decrease in the frequency of coughing attacks, asthma attacks, and a decrease in the amount of sputum secreted. The auscultation of the lungs in dynamics testified to the disappearance of dry, whistling, and buzzing wheezing in some cases.
In the process of using CHONLUTEN®, a decrease in the microscopic structures of sputum was observed: leukocytes, epithelial cells, Kurshman coils, which indicates a decrease in the inflammatory and bronchospastic manifestations of the disease.

The study of the function of external respiration showed that against the background of treatment with the use of CHONLUTEN®, the indices of bronchial patency improved (Table 1).

The effect of CHONLUTEN®on the indicators of external respiration in patients with chronic bronchitis with an asthmatic component Table 1

Indicators	Before treatment	After treatment using conventional drugs	After treatment using Chonluten®
Lung vital capacity (VC), ml	3830,8 ±312,7	3950,3±298,12	4150,4 ±265,6
Total lung capacity (OEL), ml	4800,6±334,7	5050,3±236,9	5200,7±247,4
Expiratory forced vital capacity of the lungs (EFVL), ml	2850,6±158,4	3200,7±187,5	3800,8±136,9*

* - P <0.05 compared to the values before treatment.

The results of the study of the function of external respiration indicate a sufficiently compensated pathological process in the lungs, but, at the same time, there are phenomena of impaired bronchial patency, mainly due to spasms of small bronchioles. The use of CHONLUTEN®'s positively impacted the dynamics of the development of this process.
Thus, the results of this study indicate the therapeutic efficacy of CHONLUTEN® and the advisability of its use in the complex treatment of chronic bronchitis with an asthmatic component.
In the process of using CHONLUTEN®, no side effects, complications, contraindications, or drug dependence were identified.
The studied ready-made form of CHONLUTEN® is convenient for hospitals, outpatient, and home treatment.
CHONLUTEN® can be used for therapeutic and prophylactic purposes in the form of a biologically active food supplement and in combination with any means of symptomatic and pathogenetic therapy used to treat chronic bronchitis.

CONCLUSION

Biologically active food supplement CHONLUTEN® has a normalizing effect on the functional activity of the bronchial mucosa epithelial cells, helps restore the lungs' defense mechanisms, and regulates bronchial quality.
CHONLUTEN® is well tolerated when taken orally, has no side effects, and can be used as a biologically active food supplement for therapeutic and prophylactic purposes.
CHONLUTEN® is recommended to patients with chronic non-obstructive bronchitis. It is administered orally 10-15 minutes before meals, 3 tablets 3 times a day for 15 days.
It is recommended to repeat the course of treatment in 3-6 months.
It is advisable to recommend CHONLUTEN® for therapeutic and prophylactic use and industrial production.

REFERENCES

1. Belousov Y.B., Moiseev V.S., Lepakhin V.K. Clinical Pharmacology and Pharmacotherapy: A Guide for Physicians. - M .: the Universe, 1993 .-- 398 p.
2. Mashkovsky M.D., Medicines: Pharmacotherapy for doctors, manual: 2 parts. – Vilnius: ZAO "Gamta", 1993.
3. Paleev N.R., Tsarkova L.N., Borokhov A.I. Chronic nonspecific lung diseases. - M .: Medicine, 1985 .-- 240 p.
4. Tsarkova L.N., Ilchenko V.A. Chronic nonspecific lung diseases / Diagnostics and treatment of internal diseases: A guide for doctors. Ed. F.I. Komarova. - M .: Medicine, 1991. - T. 2. - S. 106-250.

RECOMMENDATIONS FOR USE

CHONLUTEN® is recommended to normalize and correct pathological changes in the lungs resulting from various diseases, also during intensive sports. It is effective for maintaining the function of the respiratory system in elderly and senile people.
CHONLUTEN® is well tolerated by patients, and there were no side effects, complications, contraindications, or drug dependence observed.
Adults are advised to take 1-2 capsules 1-2 times daily with meals. The duration of admission is 10-30 days. It is advisable to repeat the course in 4-6 months.
Expiration date: 5 years from the date of manufacture.

Responsible executor: A.A. Veretenko

Deputy Director of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS» for clinical work, Candidate of Medical Sciences (PhD in Medical Science), Associate Professor

Executor: O.U. Raigorodsky

Chief Physician of the LLC «Medical Center of the St. Petersburg Institute of Bioregulation and Gerontology, SZO RAMS», Candidate of Medical Sciences (PhD in Medical Science)