



STUDY ON EFFICIENCY AND SAFETY
OF “ARMENICUM” IN ATHLETES

MANUKYAN N.V.

Republican Centre of Sport Medicine and Anti-Doping Service, Yerevan, Armenia

Received 1/25/2012; accepted in final form 1/02/2013

ABSTRACT

A blinded, randomized, placebo-controllable study on the efficacy and safety of “Armenicum” preparation in athletes was carried out. Eighty volunteers were invited, including 20 track and field athletes, 20 rowers, 20 cyclists and 20 football players (75 men and 5 women). After the health state examination and trial compliance verification according to criteria of inclusion/exclusion 70 athletes were selected.

The trial results suggested that the treatment course with “Armenicum capsules” formulation at a dose level of 1 capsule every 12 hours for 14 days significantly improved the athletes immunity that was usually decreased after intense trainings. This was evidenced by the increase in levels of immunoglobulin A and lymphocytes counts after “Armenicum” intake. The medication promoted increased levels of anabolic hormone insulin and decreased levels of stress hormone cortisol.

Keywords: iodine, athletes, physical work capacity, blood biochemistry indices.

INTRODUCTION

The continuous and rapid growth of sporting achievements worldwide requires the active involvement of coaches and scientists in the constant search for essentially new tools and techniques to enhance physical performance. This is firstly conditioned by the fact that trainings and competition loads of modern sport lead to serious adaptive changes, which frequently bring to the immune status disorders (moderate relative lymphocytosis, reduced immunoreactivity index, etc.) [Gleeson M., Pyne D., 2000; Gleeson M., 2002; Stacenko E., 2008]. To address the identified disorders in immune status of athletes the schemes of complex support and immunological status correction are used [Pourvagar M. et al., 2008; Stacenko E., 2008]. In terms of stabilizing the normal immunologic reactivity of the athletes’ organism it is less risky and more promising to use immunomodulators and microelements, in particular: iodine, which can stimulate metabolic processes. At the same time, in the available scientific literature we have not observed works devoted to studies on the effect of iodine, as an active ingredient, towards the organism of athletes with an analysis of their

immune status, as well as other blood parameters.

“Armenicum capsules” (hereinafter: Armenicum) preparation is one of the new immunomodulators. It belongs to “vaccination type” physiologically active polymers with iodine as one of the active components. Water-soluble polymers in combination with polysaccharides, which are used in Armenicum, allow controlled release of the active ingredient, provide targeted drug transport in the organism and prolong its effect duration. Immunomodulatory properties of Armenicum were described in numerous studies [Aleksanyan Yu. et al., 2000; Abrahamyan H., Hovhannisyan A., 2009].

It appears highly relevant to investigate the influence of Armenicum on the athletic performance, especially in sports, for which there is an evidence of immunity decrease after the exercise: rowing, middle- and long-distance running, cycling) [Niemann D., 1996; Mackinnon L., 2000].

MATERIAL AND METHODS

The trial, as a blinded, randomized, placebo-controllable study, was carried out on the basis of the Republican Centre of Sport Medicine and Anti-Doping Service. The Study Protocol was in compliance with the revised Declaration of Helsinki and authorized by Ethic Committee of Yerevan State Medical University (Order No. 3 dated 06.12.2011).

One capsule of Armenicum contains the com-

ADDRESS FOR CORRESPONDENCE:

Republican Centre of Sport Medicine and Anti-Doping Service
6 Acharyan 2nd side-street,
Yerevan 0040, Republic of Armenia
Tel.: (374 99) 299 959,
E-mail: info@armnado.am

plex of potassium iodide and iodine with dextrans. The active ingredients of the preparation involve iodine (0.0287 g), potassium iodide (0.0431 g), lithium chloride (0.0072 g), polyvinyl alcohol (0.0108 g), dextrin (0.0359 g), and sodium chloride (0.032 g). As placebo we used capsules of the same color and size as "Armenicum capsules", but without the active ingredients.

The 80 subjects – 20 track and field athletes, 20 rowers, 20 cyclists and 20 football players (total 75 men and 5 women) – were invited to take part in the study. After evaluation of the health status and matching inclusion/exclusion criteria 70 volunteers were enrolled. Each subject involved in the study underwent a physical examination and blood samples were drawn for serum chemistry and hematology according to the Study Protocol. Each volunteer received a special code number. The trial first stage involved selection of volunteers, obtaining the informed written consent, initial medical investigation (blood biochemistry, immunology, endocrinology and hematology studies), work performance and maximal oxygen uptake tests with the subsequent randomization into groups, treatment with Armenicum or placebo during 14 day at the dosage regime of 2 capsules daily (1 capsule every 12 hours), final blood analyses and tests as mentioned above.

At the second stage of our study, in 28 days after the first stage termination, generally accepted blood analyses were performed anew, and concentration of iodide anion was measured in blood of 8 volunteers (track and field athletes). During the following 21 days the volunteers were treated with Armenicum at the dose level of 4 capsules daily (2 capsules every 12 hours). At the end of the second stage, blood samples of volunteer-athletes were analyzed as well.

During the trial, all participants had the same training regime. Additionally, the participants underwent daily comprehensive physical and medical examination. After the trial completion, athletes also passed the final medical investigation.

To determine the level of physical work capacity (PWC) we used cycle ergometry test as modified by V.L. Karpman (the load capacity increased every minute for 15-20 W depending on the weight of the tested subject) [Karpman V., 1984]; the results were expressed in $kg \cdot m/min$. To perform the load test "Concept 2 Indoor Rower" ergometer (Concept2 CTS, USA) was used.

During the trial, blood concentrations of thyroid-stimulating hormone (TSH) expressed in mUI/L , triiodothyronine (T3) total in pg/dl , thyroxine (T4) total in ug/dl and free in ng/dl , cortisol in $nmol/L$, testosterone in $nmol/L$, and their ratio in %, as well as the levels of insulin in uUI/ml and immunoglobulin A (IgA) in mg/dl were measured through application of direct and concurrent solid-phase immune enzyme assay methods using ELISA kits ("DRG Instruments", Germany) on the immune enzyme automated analyzer "Stat Fax 303 Plus" ("Awareness Technology Inc.", USA).

Biochemical parameters, such as ALT and AST levels (in UI/L), the content of glucose ($mmol/L$), urea ($mmol/L$) were studied on the automated spectrophotometer "Stat Fax 3300" ("Awareness Technology Inc.", USA) using the appropriate reagents ("Delta", Armenia). Blood lactate levels were determined with the help of appropriate kits ("Roche Diagnostic", Switzerland). The results were expressed in $mmol/L$. Samples of blood were drawn from the fingers of athletes and applied to the special strips (indicator paper), which were placed into the lactometer "Accutrend Lactate" ("Roche Diagnostic", Switzerland).

Hematological parameters, such as hemoglobin (in g/L), hematokrit (%), the number of erythrocytes ($\times 10^{12}/L$), leukocytes ($\times 10^9/L$), platelets ($\times 10^9/L$), lymphocytes (%), were studied using the hematological analyzer "Sysmex. Automated Hematology Analyzer pocH-100i" ("Sysmex Corporation", Japan).

For hemoglobin determinations, whole blood samples were used, for biochemical analyses – blood serum. To obtain blood serum or plasma the sample of blood was centrifuged during 5 min at 3000 rpm. Upon centrifugation 2 ml blood serum was separated and placed into refrigerator until the analyses. For each determination we used 0.01-0.02 ml serum or plasma.

The statistical analysis was done by means of standard computer program "Statistics for Windows" (version 6.0) and Microsoft Excel 2003. All obtained results were analyzed by methods of descriptive statistics with calculation of average values, standard deviation, minimum and maximum values. For comparison of obtained results we used methods of parametrical statistics: Student's *t*-criterion with Bonferroni adjustment.

RESULTS AND DISCUSSION

There were 6 dropouts in study: five athletes from control group (placebo intake) and one athlete from the experimental group (Armenicum treatment) were withdrawn. The reason for dropouts was inability of athletes to continue exercising due to the sport injuries or diseases.

The comparison of blood indices that are most commonly used in sports medicine before and after taking the Armericum at a dose of 2 capsules daily showed that in the control group there were no statistically significant changes in values of the studied biochemical, hematological, hormonal, and other parameters.

TABLE 1.

Changes of blood parameters in participants of the study 1st stage
(after treatment with Armericum at 2 capsules daily; n=34)

Parameterc	Mean values		Mean for difference	P
	Before	After		
Age, years	21.32 ± 4.49	21.32 ± 4.49	0	-
Height, cm	175.27 ± 6.29	175.27 ± 6.29	0	-
Weight, kg	76.45 ± 1.013	76.68 ± 1.002	-0.2230 ± 1.424	0,876
BMI, kg/m ²	25.31 ± 2.153	24.97 ± 1,890	-0.34± 0.431	0.845
ALT, UI/L	20.31 ± 0.4535	20.80 ± 0.7150	-0.495± 0.846	0.561
AST, UI/L	17.01 ± 1.425	16.19 ± 1.221	0.8256 ± 1.87	0.6614
Glucose, mmol/L	4.052 ± 0.059	3.936 ± 0.124	0.1165 ± 0.137	0.4011
Lactate, mmol/L	2.555 ± 0.092	2.327 ± 0.0727	0.2276 ± 0.118	0.0581
Urea, mmol/L	3.834 ± 0.145	4.059 ± 0.203	-0.225± 0.250	0.3722
Hemoglobin, g/L	156.3 ± 1.198	160.2 ± 1.397	-3.874 ± 1.840	0.0391*
Hematokrit, %	45.14 ± 0.284	44.73 ± 0.538	0.405 ± 0.609	0.5079
Erythrocytes, x 10 ¹² /L	5.391 ± 0.053	5.561 ± 0.044	-0.170 ± 0.069	0.0174*
Platelets, x 10 ⁹ /L	227.3 ± 8.157	233.3 ± 8.673	-5.950 ± 11.91	0.6187
Lymphocytes, %	30.87 ± 1.703	35.96 ± 1.867	5.093 ± 2.52	0.0475*
Leukocytes, x 10 ⁹ /L	6.114 ± 0.228	6.401 ± 0.141	-0.287 ± 0.269	0.2895
IgA, mg/dl	135.2 ± 6.397	159.6 ± 7.812	-24.44 ± 10.10	0.0183*
Insulin, uUI/ml	11.21 ± 0.662	23.41 ± 3.960	-12.20 ± 4.015	0.0034**
Cortisol, nmol/L	297.8 ± 11.54	293.6 ± 25.86	4.150 ± 28.32	0.8839
TSH, mUI/L	1.498 ± 0.098	2.805 ± 0.185	-1.307 ± 0.21	<0.0001***
T3, pg/dl	0.956 ± 0.038	0.931± 0.033	0.0249± 0.051	0.6265
T4 _{free} , ng/dl	1.471 ± 0.055	1.390 ± 0.067	0.082 ± 0.087	0.3556
T4 _{total} , ug/dl	9.360 ± 0.322	9.744 ± 0.263	-0.384± 0.416	0.3593
Testosterone, nmol/L	16.37 ± 1.208	17.97 ± 1.220	-1.599 ± 1.717	0.3549
Testosterone/Cortisol, %	5.720 ± 0.4427	7.844 ± 0.8264	-2.123 ± 0.93	0.0268
PWC _{170'} , kg·m/min	1223,28 ± 12,94	1324,84 ± 62,40	-101.6 ± 14.15	0.0008**
VO _{max} , ml/min/kg	49,81± 4,30	51,58 ± 5,10	-2.38.6±0.81	0.1613

NOTE: * statistically significant changes.

The study results showed that no deviations from norm were recorded in the results of the electrocardiography at rest and after the cycle ergometry test in the experimental and control groups. In 3 minutes after the end of the test, both groups showed blood pressure restoring to its baseline.

In the experimental group, the value of PWC significantly increased from $1223.28 \pm 1294 \text{ kg}\cdot\text{m}/\text{min}$ to $1324.84 \pm 62.40 \text{ kg}\cdot\text{m}/\text{min}$ ($p=0.0027$), while in the control group no significant differences were recorded. The values of PWC in athletes of control group were insignificantly decreased (Table 1). The same pattern was observed for maximum oxygen consumption – volume of oxygen (VO_{max}). The difference in VO_{max} values before and after Armenicum intake was less pronounced (4%) than in the study on PWC_{170} (8.5%). In the experimental group, VO_{max} increased insignificantly from 49.81 ± 4.30 to $51.58 \pm 5.10 \text{ ml}/\text{min}/\text{kg}$. In the control group the value of VO_{max} remained actually unchanged before and after treatment with placebo and made approximately $48.5 \pm 4.5 \text{ ml}/\text{min}/\text{kg}$ (Table 1).

Unlike the control, in the experimental group we observed significant differences in the levels of the studied blood parameters; however, the changes in biochemical parameters were insignificant (Table 1).

Significant changes were also noted in the certain hematological parameters. After a course of treatment with Armenicum the level of hemoglobin was significantly increased from $156.3 \text{ g}/\text{L}$ to $160.2 \text{ g}/\text{L}$, erythrocytes content increased from $5.39 \times 10^{12}/\text{L}$ to $5.56 \times 10^{12}/\text{L}$. The level of hematocrit before and after treatment practically did not change and made $\sim 45\%$ (Table 1).

It is well known that at iodine deficiency anemia is often observed, leading to decreased blood hemoglobin content. Currently, it is established that iodine can catalyze the synthesis of hemoglobin. In particular, it was proved that upon administration of iodine to piglets by implantation at a dose of 2-4 mg per animal there was a significant increase in blood hemoglobin levels by 18-30% [Bulgakov A., Shevchenko N., 1999].

The trial results also showed a significant increase in blood insulin levels from $11.21 \text{ uUI}/\text{ml}$ to $23.41 \text{ uUI}/\text{ml}$. The blood glucose levels remained practically unchanged and were within the normal range, approximately at $4 \text{ mmol}/\text{L}$. Changes in the immune system were characterized by increased

TABLE 2.

Changes of blood TSH levels in participants of the study 1st stage ($m\text{UI}/\text{L}$)

Participant identification code	before	after	5 days after the end of treatment
3	1.30	4.02	1.3
12	1.30	4.10	2.1
17	2.80	4.10	3.4
23	1.60	5.50	2.5
31	1.80	4.90	1.8

levels of IgA and lymphocytes number. The level of IgA was significantly increased from $135 \text{ mg}/\text{dl}$ to $160 \text{ mg}/\text{dl}$ ($p=0.0183$), and the content of lymphocytes in blood increased by 5.1% (Table 1).

In the course of our study an increase of anabolic index (2%) and PWC (11%) was recorded in athletes; however, the increase never reached significant values (Table 1).

Significant changes occurred also in the immune and endocrine systems of volunteers. Firstly, the sharp increase of TSH from $1.5 \text{ mUI}/\text{L}$ to $2.8 \text{ mUI}/\text{L}$ should be mentioned; however, the level of this hormone remained within the normal range ($0.4\text{-}4.0 \text{ mUI}/\text{L}$) (Table 2). After treatment with Armenicum we detected TSH levels above the norm only in five athletes. The repeated analysis of thyroid hormones performed in 5 days after the end of the treatment course showed that the level of TSH recovered to the initial values (Table 2).

The statistical analysis of indices significantly changed after Armenicum intake was done by the method of comparing quantitative traits, using Student's *t*-test with Bonferroni adjustment. The results thus obtained showed that erythrocytes count and hemoglobin levels before treatment with Armenicum were the same in both groups. In the control group after administration of placebo these indices did not change (Figure 1). In the experimental group a significant increase in levels of both parameters was recorded.

As evident from Figure 2, IgA levels in control and experimental groups before placebo and Armenicum intake did not significantly differ. After administration of placebo the values of these indices in control group were slightly decreased. In the

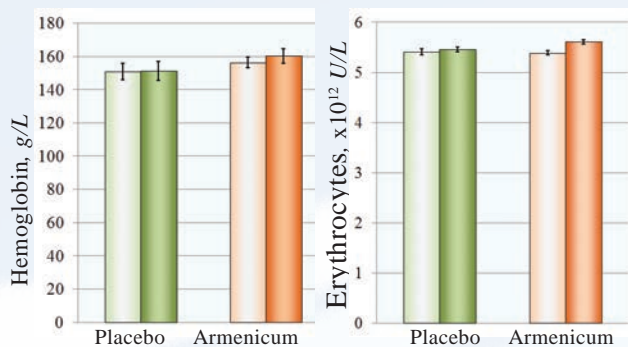


FIGURE 1. Changes in levels of hemoglobin and erythrocytes content before (□, □) and after (■, ■) placebo and Armenicum intake.

experimental group, we observed a significant increase of IgA levels. The same changes were noted for lymphocytes as well.

According to data obtained, after placebo intake the level of insulin decreased in control group, but there was its significant increase in the experimental group. After treatment with Armenicum the values of studied parameter were above those in control group (Figure 2).

It is known that changes in the rate of protein synthesis observed after high-intensity physical training are followed with a 3.7 times decrease in anabolic hormone insulin, as well as an increase in concentration of catabolic hormones, cortisol and aldosterone, in blood plasma of rats in comparison with the baseline. Back in 1970, it was established that after the physical exercise along with cortisol increase the decrease of insulin concentration simultaneously occurred. Thus, in rats after intense (extreme) swimming the cortisol/insulin ratio increased 2.5 times [Panin L., 1983].

Insulin secretion from the pancreas is associated with hormones concentration in blood, the activity of

the autonomic nervous system and the action of other hormones, e.g., testosterone. Insulin is the main anabolic hormone that promotes the accumulation of carbohydrates, proteins, and lipids in the cells through its effects on liver, adipose tissue and skeletal muscles. Studies on insulin kinetics after the stress recorded its biphasic nature, consisting in the initial inhibition of insulin secretion in the early period after the stress through the activity of the autonomic nervous system, and then in its transition to a normal or enhanced release (insulin resistance phase).

Thus, the obtained results suggest the conclusion that Armenicum treatment course at a dose level of 1 capsule every 12 hours during 14 days promoted the enhanced immunity and increased PWC of athletes by increasing levels of hemoglobin and lymphocytes. Increased levels of anabolic hormones and reduced concentration of stress hormone, cortisol, were recorded in investigated cohort.

At the second phase of the study, in 28 days after the end of the first phase, 8 volunteers (mean age: 20.25 ± 1.82 years; BMI: 24.42 ± 1.715 kg/m²) were treated with Armenicum at the daily dose level of 4 capsules during 21 days; the preparation was taken by 2 capsules twice a day: at 9 a.m. and 21 p.m. Prior to and upon the study termination blood was sampled for biochemical, endocrinological and hematological tests, as well as for determination of iodide anion concentration in blood (Table 3).

The outcomes of statistical analysis showed that, in contrast to the first phase of the study, increased doses of Armenicum did not lead to significant changes in blood parameters of athletes. As obvious from Table 3, the significant changes were registered only for levels of TSH and T4_{free}. The levels of insulin, IgA, lymphocytes and hemo-

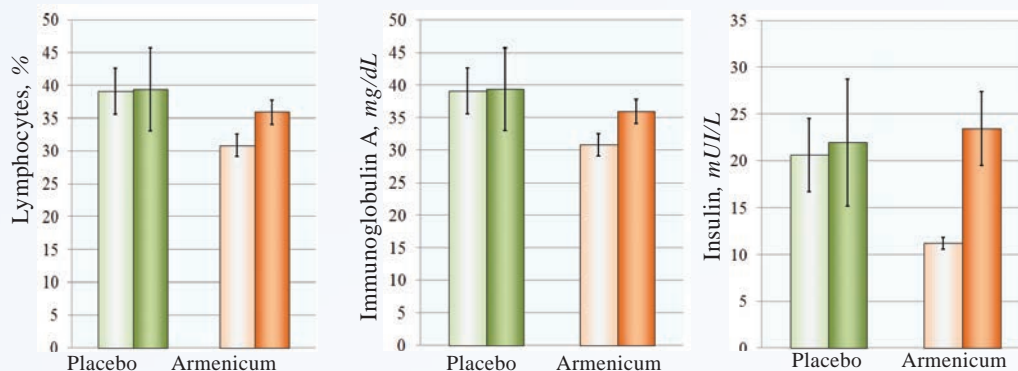


FIGURE 2. Changes in lymphocytes, Immunoglobulin A and insulin levels before (□, □) and after (■, ■) placebo and Armenicum intake.

globin, as well as other investigated parameters practically did not change (Table 3).

In the course of the study we found that the concentration of iodide anion was increased in the blood associated with an increased level of TSH in 80% cases. In all trial participants an increase of iodide anion concentration in blood was recorded after the intake of capsules. However, no toxic effects or adverse reactions were observed after Armenicum intake (Table 4).

The comparison of results obtained in athletes

participating in the first and second stages of the study showed that the increase of Armenicum dose level did not lead to significant changes in the levels of hemoglobin, erythrocytes, IgA and insulin.

Despite the fact that Armenicum intake at dose level of 4 capsules daily is safe for athletes, to achieve the best effect, it is desirable to use Armenicum at a dose of 1 capsule every 12 hours for 14 days.

During the entire study, athletes of the experimental group (Armenicum intake) consistently reported well-being. In the daily medical monitoring

TABLE 3.

Changes of blood parameters in participants of the study 2nd stage (after treatment with Armenicum at 4 capsules daily; n=8)

Parameters	Mean values		P
	Before	Before	
Age, year	20.25 ± 1.82	-	-
Weight, kg	74.87 ± 9.05	73.76 ± 8.97	0.851
Height, cm	177.85 ± 11.02	-	-
BMI, kg/m ²	24.42 ± 1.715	25.51 ± 1.65	0.8401
ALT, UI/L	21.1 ± 2.25	24.4 ± 2.64	0.358
AST, UI/L	24.6 ± 2.86	23.9 ± 1.71	0.8393
Glucose, mmol/L	4.44 ± 0.112	4.44 ± 0.271	1 0000
Urea, mmol/L	3.31 ± 0.281	3.24 ± 0.281	0.8529
Hemoglobin, g/L	156 ± 4.40	161 ± 4.74	0.4738
Hematokrit, %	45.8 ± 0.571	46.9 ± 1.05	0.4
Erythrocytes, x 10 ¹² /L	5.33 ± 0.0842	5.44 ± 0.147	0.5351
Platelets, x 10 ⁹ /L	205 ± 13.6	220 ± 19.5	0.6
Lymphocytes, %	34.3 ± 1.95	31.4 ± 3.15	0.4
Leukocytes, x 10 ⁹ /L	6.54 ± 0.427	7.51 ± 0.593	0.2033
IgA, mg/dl	105 ± 12.2	80.4 ± 10.2	0.1516
Insulin, uUI/ml	11.4 ± 1.82	9.88 ± 1.15	0.4833
Cortisol, nmol/L	419 ± 30.2	362 ± 23.6	0.1569
TSH, mUI/L	1.10 ± 0.204	3.14 ± 0.833	0.0323*
T3, pg/dl	0.800 ± 0.0732	0.775 ± 0.0648	0.8018
T4 _{free} , ng/dl	1.41 ± 0.0743	1.15 ± 0.0535	0.0124*
T4 _{total} , ug/dl	9.050 ± 0.4932	9.020 ± 0.3735	0.962
Testosterone, mmol/L	15.7 ± 2.29	14.8 ± 2.07	0.7841
Iodide anion, mcg/ml	0.0589 ± 0.0272	0.350 ± 0.102	0.0156*

NOTE: * statistically significant changes.

TABLE 4.
Changes in blood levels of TSH and iodide anion in participants of the study 2nd stage (after treatment with Armenicum at 4 capsules daily)

Participant identification code	TSH, mUI/l		Iodide anion, mcg/ml		Character of changes	
	before	after	before	after	TSH,	Iodide anion,
1	1.3	2.2	0.244	0.027	↑	↓
2	2.1	3.4	0.054	0.445	↓	↑
3	0.6	4.5	0.06	0.411	↑	↑
4	0.7	0.5	0.021	0.049	↓	↑
5	1.8	7.9	0.035	0.258	↑	↑
6	0.8	3.4	0.013	0.598	↑	↑
7	0.9	2.5	0.033	0.867	↑	↑
8	0.6	0.7	0.011	0.147	↑	↑
Mean	1.1	3.1375	0.059	0.350	0.059	0.350
STD.	0.57	2.35	0.077	0.289	0.077	0.289
CV%	52.33	75.09	130.57	82.62	130.57	82.62

conducted by team doctors, as well as doctors of Sports Schools, where the participant athletes were trained, neither health complaints were registered, nor side effects revealed.

All studied biochemical parameters, except for 5 cases with increased TSH levels, remained within the normal range during the entire period of investigation. Dropout of athletes from the study was not associated with the action of Armenicum.

CONCLUSION

The treatment course with “Armenicum capsules” at a dose level of 1 capsule every 12 hours for 14 days significantly increased the athletes immunity, which was usually decreased after intense workouts. The increase of Armenicum dose level did not lead to enhanced efficacy of the medication. At higher dose the levels of insulin, IgA, lymphocytes and hemoglobin, as well as other investigated parameters practically did not change. Thus, the Armenicum treatment course did not cause any side effects and/or adverse reactions and was safe for athletes.

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