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COMPARISON OF THE EFFECT OF LIPEXAN HERBAL MEDICINE PRODUCT WITH PLACEBO AND GEMFIBROZIL ON BLOOD LIPID INDICES

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ABSTRACT

Introduction: Increased blood lipids are an important factor in the occurrence of cardiovascular diseases and heart attacks in humans. The aim of this study is to compare the effect of the traditional medicine product Lipexan with placebo along with Gemfibrozil on blood lipid indicators.

Material and methods: This study was conducted as a double-blind randomized clinical trial with a parallel design, on 109 patients with hyperlipidemia. After entering the study, patients were randomly divided into two groups receiving Lipexan herbal capsules (containing garlic, sumac, apple cider vinegar, fenugreek and dill) and placebo capsules. Both groups received Gemfibrozil capsules at the same time and were prescribed the same diet. The duration of treatment was 40 days. The lipid profile of the patients was checked before and after taking the drugs.

Results: In the Lipexan drug treatment group, the average blood triglyceride before taking the drug was 362.2 mg/dl, which reached 243.1 mg/dl after taking the drug. Also, the average blood cholesterol before and after taking the drug was 201.4 and 187.7, respectively. Statistically, there was a significant decrease in triglyceride, total cholesterol, Low Density Lipoprotein, High Density Lipoprotein, fasting blood sugar and alkaline Phosphatase after taking Lipexan drug ($P < 0.05$).

Conclusion: The present study shows that Lipexan herbal capsule is effective in reducing blood fats and lipid profile in hyperlipidemia patients compared to placebo capsule.

KEYWORDS: Lipexan, Gemfibrozil, Cholesterol, Triglyceride, LDL, HDL

INTRODUCTION

Cardiovascular diseases are known as one of the most common preventable chronic diseases and the most important cause of death in Iran and the world. Also, due to many economic losses and the relative

disability of active people in the society, they are considered as a major problem [Kazemi T et al., 2006]. Research shows that the use of diets with high levels of carbohydrates and fats can increase

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the level of harmful plasma lipids and lipoproteins. The use of these diets increases the level of triglycerides, cholesterol and low density lipoprotein (LDL) and decreases the level of high density lipoprotein (HDL), which in total increases the risk of cardiovascular diseases [Piri M et al., 2010].

Cardiovascular diseases are often caused by blockage of arteries due to atherosclerosis [Rafati A et al., 2006]. One of the main risk factors in the occurrence of atherosclerosis phenomenon, followed by cardiovascular diseases, is hyperlipidemia [Kazemi T et al., 2006]. The only independent and necessary factor in the emergence of atherosclerosis is the high level of LDL cholesterol. So that even in the presence of other major risk factors, at total cholesterol levels less than 150 mg/dl, atherosclerotic events are rare [Delfan B et al., 2010]. Coronary heart disease is one of the most important cardiovascular diseases. So that 50% of cardiac deaths are caused by coronary heart disease and the main cause is atherosclerosis [Parastouei K et al., 2006]. The effective factors in the development of coronary artery disease usually include hypercholesterolemia, especially high levels of oxidized LDL and HDL, hypertension, diabetes mellitus, decreased fibrinolytic activity, increased serum fibrinogen, and increased platelet aggregation [Emami F, et al., 2006]. Cardiovascular diseases are often caused by blockage of arteries due to atherosclerosis [Rafati A et al., 2006]. One of the main risk factors in the occurrence of atherosclerosis phenomenon, followed by cardiovascular diseases, is hyperlipidemia [Kazemi T et al., 2006]. The only independent and necessary factor in the emergence of atherosclerosis is the high level of LDL cholesterol. So that even in the presence of other major risk factors, at total cholesterol levels less than 150 mg/dl, atherosclerotic events are rare [Delfan B et al., 2010]. Coronary heart disease is one of the most important cardiovascular diseases. So that 50% of cardiac deaths are caused by coronary heart disease and its main cause is arteriosclerosis [Parastouei K et al., 2006]. The effective factors in the development of coronary artery disease usually include hypercholesterolemia, especially high levels of oxidized LDL and HDL, hypertension, diabetes mellitus, decreased fibrinolytic activity, increased serum fibrinogen, and increased platelet aggregation [Emami F. et al. 2006].

Changes in diet and lifestyle are considered as

the first line of treatment [Parhofer KG, Laufs U., 2019]. In the next steps fenofibrate are used, such as Gemfibrozil, Omega-3 and statin drugs. The use of Gemfibrozil can be effective in reducing triglycerides [Kesäniemi YA, Grundy S., 1984]. Today, a wide world trust has been directed towards the use of herbal medicines. Traditional medicine in Iran has an ancient history and the variety of plant cultivation in Iran has made it easy to obtain all kinds of medicinal plants [Yousefi E et al., 2015, Moradkhani T et al., 2017].

Fenugreek is among the most important medicinal plants in the world due to the production of medicinal alkaloids, steroid compounds, saponins and high power in reducing blood fat. Nicotinic acid trigonelline is one of the most important metabolites of fenugreek plant, which is also effective in treating and reducing blood cholesterol and triglycerides [Kassae SN, Kassae SM., 2019]. Consumption of fenugreek also has a protective effect by increasing the amino acid 4-hydroxyisoleucine to increase insulin secretion, improve glucose transfer into the cell, improve lipid metabolism and reduce the level of oxidative stress on the cell [Hosseini SA et al., 2023].

Garlic contains compounds such as starch, mucilage, protein and sugar. Due to having sources of phytochemicals, garlic can play a significant role in the treatment of cardiovascular disease, lowering blood pressure, lowering blood cholesterol and triglycerides, and reducing platelet aggregation [Moosavi T et al., 2016]. Studies have shown that garlic can control blood fat by inhibiting liver enzymes responsible for cholesterol synthesis [Mahmoudi M et al., 2007].

Sumac contains antioxidants, flavonoids and hydrolyzable tannins. Glycoprotein extracted from sumac fruit also reduces total cholesterol, triglycerides, LDL and increases antioxidant capacity [Setorkil M et al., 2012]. Dill is used as a rich source of antioxidants by having various compounds such as flavonoids and quercetin. Various studies have shown its reducing effect on triglycerides and blood cholesterol [Askari M et al., 2016].

Also, studies have stated that the consumption of acetic acid (the main ingredient of vinegar) and apple cider vinegar can reduce fasting blood triglyceride and cholesterol levels [Shishehbor F et al., 2006].

The effects of the mentioned plants on reducing

blood fat have been studied in several studies, but there is no similar study on the natural composition of the above components. Lipexan herbal medicine for blood lipids contains garlic, sumac, apple cider vinegar, fenugreek and dill, which is made with a dose of 750 mg. This study was conducted with the aim of comparing the effect of lipexan herbal medicine product with placebo along with Gemfibrozil on blood lipid indices.

MATERIALS AND METHODS

Study design: This study was conducted as a double-blind randomized clinical trial with a control group, on patients with hyperlipidemia referred to the Cardiology and Internal Medicine Clinic of Qom city.

The inclusion criteria were plasma cholesterol level more than 193 mg/dl, LDL plasma level more than 160 mg/dl, and average fasting blood triglyceride plasma level between 200 and 499 mg/dl. Exclusion criteria include history of treatment for hyperlipidemia, hypercholesterolemia, and secondary hypertriglyceridemia, nephrotic syndrome, obstructive jaundice, hypothyroidism, Cushing's syndrome, anorexia nervosa, thiazide diuretics, cyclosporine, obesity (BMI $\geq$ 40), diet full of Saturated fats and carbohydrates, physical inactivity, alcohol consumption, human immunodeficiency virus (HIV), nephrotic syndrome, dialysis, hypothyroidism, Cushing's syndrome, anorexia nervosa, acute spinal cord injury, systemic lupus erythematosus (SLE), myeloma, drug use (thiazides, antiretrovirals, glucocorticoids, estrogens, antibiotics) psychotics and beta blockers...), mixed hyperlipidemia, type 2 diabetes, hypersensitivity, primary biliary cirrhosis, severe liver or kidney disorder, pregnancy and breastfeeding.

Sample size: The sample size was calculated based on the results of the effects of Antom tablets containing dill on the blood cholesterol of patients before and after treatment [Piri M et al., 2010]. Considering the confidence of 95% and the test power of 0.8, the minimum required sample was calculated as 43 people in each group.

Data collection: In this study, 180 patients with cholesterol plasma level more than 193 mg/dl, LDL plasma level more than 160 mg/dl, and average fasting blood triglyceride plasma level between 200 and 499 mg/dl were selected. Patients

were checked according to the exclusion criteria and 153 patients remained. After the selection, a written consent was obtained from them. Demographic information, history of underlying diseases and daily physical activity, primary paraclinical tests including fasting blood sugar (FBS), triglycerides (TG), total cholesterol (TC), high density lipoprotein (HDL), Serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), alkaline phosphatase (ALK), potassium (K), blood urea nitrogen (BUN) and creatinine (CR) of the patients were recorded. Then they were randomly assigned a block with a ratio of 2 to 1 in one of the treatment groups including herbal medicine and placebo. The herbal blood lipid medicine contains garlic, sumac, apple vinegar, fenugreek and dill, which was made under the brand name Lipexan with a dose of 750 mg. The placebo capsule contained Avicel, and both capsules were made by Booali Daroo Pharmaceutical Company and were packed in the same vials and given to the patients. This substance has no effect on blood fat.

The length of the treatment period was 40 days, during which both groups of patients took 3 Lipexan herbal capsules daily along with a 300 mg Gemfibrozil capsule manufactured by Pars Daroo Pharmaceutical Company. The same diet was recommended to the patients. 109 patients cooperated until the end, when all the above tests were repeated in the same medical diagnosis laboratory.

How to analyze information: First, frequency tables were calculated for qualitative variables and mean and standard deviation were calculated for quantitative variables. Kolmogorov-Smirnov test was used to check the normality of quantitative variables. In univariate analysis, independent T-test or Mann-Whitney test was used to compare groups. To check the changes of parameters in a group before and after treatment, the dependent T test or Wilcoxon signed-rank test was used. For qualitative values, chi-square or McNemar test was used. Covariance analysis was used for multivariate analysis and removing the effects of confounding variables.

RESULTS

In this study, 180 patients who met the entry conditions were included in the study. Of these, 27

people met at least one of the exclusion conditions and were excluded from the study.

The remaining 153 patients were divided into two groups: a group taking the drug Lipexan (103 patients) and a control group of 50 patients taking placebo. During the treatment process, 44 people (28 and 16 patients) were excluded from the study due to not taking the medicine properly and not following the treatment protocol. Finally, the study was conducted on 109 patients 39.4% of patients were female and the rest were male. 75 people (68.8%) of the participants remained in the Lipexan drug group and 34 people (31.2%) remained in the placebo group. The average age of the intervention group was 44.9 years and the placebo group was 44.7 years. The average TG and blood cholesterol before taking the drugs were 362.2 and 201.4 mg/dl in the case group and 364.4 and 211.8 mg/dl in the control group, respectively. Demographic distribution and anthropometric indices and the results of initial tests except for ALK in the two study groups at the beginning of treatment had no statistically significant difference ($p < 0.05$) (Table 1)

In terms of all the risk factors of the disease, including stressful work, physical activity, use of blood lipid-lowering drugs, smoking, diet, angina pectoris, etc., there was no statistically significant difference between the two groups ($P < 0.05$). (Data not shown).

In the Lipexan drug group, the average blood TG before taking the drug was 362.2 mg/dl, which reached 243.1 mg/dl after taking the drug. The average blood cholesterol before and after taking the drug was 201.4 mg/dl and 187.7 mg/dl, respectively. Statistically, a significant decrease in TG, LDL, HDL, cholesterol, FBS and ALK was seen after taking the herbal medicine along with Gemfibrozil ($P < 0.05$). In the group of patients receiving placebo, the average blood TG before taking the drug was 364.4 mg/dl, which reached 0.298 mg/dl after taking the placebo. Statistically, a significant decrease in blood TG and cholesterol was seen after taking placebo along with Gemfibrozil ($P < 0.01$), while blood creatinine increased by 0.1 units, which is statistically significant. ($P = 0.34$) (Table 2).

In the placebo group, the average TG reduction was 66.4 mg/dl, while in the herbal medicine group, this number was 119.7 mg/dl. Also, the reduction of blood sugar after taking the drug in the placebo and Lipexan groups was 4.3 mg/dl and 9.1

TABLE 1.

Frequency distribution, mean and standard deviation of Demographic variables and laboratory parameters at the beginning of treatment in the two study groups

Variables	Intervention groups		P.Value
	Lipexan n (%)	Placebo n (%)	
Sex	female	31 (41.3)	0.55
	male	44(58.7)	
Job	housewife	28(37.3)	0.49
	Self-employer	18(24)	
	Employee	21(28)	
	Retired	8(10.7)	
Age($\pm$ SD)(year)	44.9 $\pm$ 9.4	44.7 $\pm$ 9.67	0.925
Height(cm)	170 $\pm$ 9.8	171.6 $\pm$ 8.2	0.477
Weight(kg)	84.1 $\pm$ 14.7	86.8 $\pm$ 20.2	0.434
BMI(kg/m ²)	28.4 $\pm$ 9.2	29.5 $\pm$ 6.9	0.609
TG(mg/dl)	362.2 $\pm$ 110.1	364.4 $\pm$ 74.8	0.916
LDL(mg/dl)	101 $\pm$ 39.4	105.7 $\pm$ 34.7	0.568
HDL(mg/dl)	39.5 $\pm$ 11.7	40.1 $\pm$ 11.3	0.788
CHOL(mg/dl)	201.4 $\pm$ 41.4	211.8 $\pm$ 40.6	0.225
FBS(mg/dl)	123.5 $\pm$ 58.6	115.6 $\pm$ 45.2	0.494
SGPT(iu/l)	35.6 $\pm$ 32.2	25.9 $\pm$ 11.1	0.142
ALK(iu/l)	189.9 $\pm$ 52.3	161.5 $\pm$ 48.5	0.030
SGOT(iu/l)	25.4 $\pm$ 13.7	20.1 $\pm$ 5.5	0.058
BUN(mg/dl)	26.2 $\pm$ 8.2	25.0 $\pm$ 10.6	0.555
CR(mg/dl)	1.0 $\pm$ 0.2	1.0 $\pm$ 0.1	0.892
K(mEq/l)	4.1 $\pm$ 0.3	4.1 $\pm$ 0.3	0.801
NA(mEq/l)	139.6 $\pm$ 2.25	140.3 $\pm$ 3.2	0.372
Sample size	375	34	--

NOTES: BMI- Body Mass Index, LDL- Low Density Lipoprotein, HDL- High Density Lipoprotein, ALK- Alkaline Phosphatase, TG- Triglyceride, CHOL- Total Cholesterol, FBS- Fasting Blood Sugar, SGPT- Serum Glutamic Pyruvic Transaminase, SGOT- Serum Glutamic Oxaloacetic Transaminase, BUN- Blood Urea Nitrogen, CR- Creatinine, K- Potassium

mg/dl, respectively. In the group of herbal capsule users, an increase of 1.4 units was seen in HDL, while in the placebo group, only 0.9 units of increase were seen. Of course, there was no statistically significant difference in the reduction of other laboratory parameters after taking the drug between the two groups ($P < 0.05$). The results of covariance analysis also showed that by removing the effect of initial values, the effect of treatment groups on the reduction of blood TG and LDL is statistically significant (Table 3). No special side effects were observed after taking the drug in the two treatment groups.

TABLE 2.

Mean and standard deviation of laboratory results before and after treatment
in treatment and control groups

Laboratory results	Lipexan group		P ¹ .Value	Placebo group		P ¹ .Value
	Before (± SD)	After (± SD)		Before (± SD)	After (± SD)	
TG(mg/dl)	362.2±110.1	243.1±88.9	<0.001	364.4±74.8	298.0±104.3	0.001
LDL(mg/dl)	101.0±39.4	89.2±37.5	<0.001	105.7±34.7	104.6±37.8	0.805
HDL(mg/dl)	39.5±11.7	43.6±11.6	0.002	40.1±11.3	41.1±8.7	0.597
CHOL(mg/dl)	201.4±41.4	187.7±41.0	0.001	211.8±40.6	195.7±44.8	0.004
FBS(mg/dl)	123.5±58.6	114.3±45.2	0.036	115.6±45.2	111.2±33.1	0.268
SGPT(Iu/l)	35.6±32.2	31.1±21.9	0.149	25.9±11.1	25.0±11.3	0.439
ALK(Iu/l)	189.9±52.3	178.0±53.2	0.011	161.5±48.5	160.3±48.5	0.690
SGOT(Iu/l)	25.4±13.7	26.0±12.4	0.742	20.1±5.5	19.2±4.0	0.348
BUN(mg/dl)	26.2±8.2	26.8±10.0	0.575	25.0±10.6	24.3±9.8	0.606
CR(mg/dl)	1.0±0.2	1.0±0.3	0.814	1.0±0.1	1.1±0.2	0.024
K(mEq/l)	4.1±0.3	4.2±0.3	0.766	4.1±0.3	4.0±0.6	0.657
NA(mEq/l)	139.6±2.3	140.1±2.8	0.184	140.3±3.2	139.5±2.6	0.252

NOTES: Data was shown by mean and standard deviation 1 Paired sample T test was applied, Abbreviations are presented in Table 1

TABLE 3.

Mean and standard deviation of the reduction of blood test
results before and after medicine consumption in two study
groups

Laboratory results	study groups				p ¹	p ²
	Lipexan		Placebo			
	(± SD)	PR	(± SD)	PR		
TG(mg/dl)	119.7±105.1	32.2	66.4±106.8	18.2	0.016	0.002
LDL(mg/dl)	11.8±22.5	8.7	1.1±26.1	1.04	0.038	0.018
HDL(mg/dl)	-4.1±11.0	-10.4	-0.9±10.1	-2.3	0.164	0.142
CHOL(mg/dl)	13.7±35.8	6.8	16.1±29.9	7.6	0.734	0.894
FBS(mg/dl)	9.1±36.5	7.4	4.3±22.3	3.8	0.488	0.744
SGPT(Iu/l)	4.4±24.1	12.7	0.9±6.3	3.8	0.293	0.646
ALK(Iu/l)	11.9±34.7	6.3	102±14.2	0.8	0.054	0.059
SGOT(Iu/l)	-0.5±12.5	-4.4	0.8±4.6	2.3	0.448	0.434
BUN(mg/dl)	-0.6±9.7	-2.5	0.6±7.3	2.7	0.492	0.321
CR(mg/dl)	0.005±0.1	0.5	-0.06±0.1	-6.1	0.069	0.68
K(mEq/l)	-0.01±0.3	0.25	0.09±0.8	2.2	0.476	0.327
NA(mEq/l)	0.83±2.86	-0.35	-0.49±2.4	0.6	0.076	0.126

NOTES: Data was shown by mean and standard deviation, P¹= Significant level of time effect in repeated measures analysis of variance P²= Significant level of time*group effect in repeated measured analysis of variance, Abbreviations are presented in Table 1, PR - Percentage reduction

Discussion:

In most of the studies conducted in the field of heart diseases, the level of serum lipids in the fasting state has been investigated as one of the risk factors for the development of cardiovascular diseases [Shishehbor F et al., 2006].

Seyed Ali Hosseini and his colleagues found out by experimenting on diabetic rats that swimming exercise plus the consumption of fenugreek can significantly reduce glucose, insulin, and insulin resistance, LDL, VLDL, TG and TC as well as increase HDL (p<.05). [Hosseini SA et al., 2023] The exact mechanism of the effect of fenugreek on cellular metabolism is not yet fully known [Bruce-Keller AJ et al., 2020], however, polyphenols and saponins in fenugreek seem to play a major role. in reducing blood fat levels [Heshmat-Ghahdarijani K et al., 2020]. In this regard, a study showed that the administration of fenugreek (2% of the diet) for 16 weeks increases weight, regulates LDL, HDL and blood sugar [Bruce-Keller AJ et al., 2020].

Another study stated that by consuming fenugreek seed powder twice a day (a total of 100 grams), the level of serum total cholesterol, LDL and VLDL cholesterol, and triglycerides are significantly reduced [Sharma R D et al., 1990].

Yousefi et al., in their study, which was conducted as a randomized clinical trial, compared the effect of fenugreek powder with placebo in patients with hyperlipidemia. Their results showed that there is a statistically significant difference in the lipid profile in the group receiving fenugreek compared to the control group. The level of HDL did not increase significantly, which was not consistent with the results of the present study [Yousefi E et al., 2015]. In the study by Sharma et al., HDL remained unchanged with the consumption of this plant [Fallah Hosseini H et al., 2005]. Among the causes of this difference, we can mention the various compounds of the drug Lipexan, which have caused a synergistic effect with the fenugreek plant.

In a review study, Fallah Hosseini et al investigated the effect of different herbal medicines on blood lipid factors. Among the investigated cases, fenugreek and garlic are among the compounds of Lipexan. According to this study, fenugreek reduces blood cholesterol and triglyceride levels. The only side effect of this plant is mild digestive disorders in case of excessive consumption. In animal studies, no toxic effects have been observed with the consumption of this plant. Fenugreek seed extract has a stimulating effect on the uterus of guinea pigs, which is why it is better for pregnant women to consume it with caution and according to the doctor's opinion. Also, the consumption of this plant is not recommended for children, kidney and liver patients [Fallah Hosseini H et al., 2005].

This study further stated that some studies conducted during the 1980s and 1990s show the reduction of blood cholesterol levels with the consumption of garlic. Although some newer studies have rejected this issue [Fallah Hosseini H et al., 2005]. In a study on 46 patients with high blood cholesterol, taking garlic coated tablets for 12 weeks significantly reduced cholesterol and LDL. Unlike the present study, HDL cholesterol increased significantly in the placebo group compared to the garlic group, and no significant difference was observed in triglycerides or LDL/HDL ratio [Kannar D et al., 2001]. This difference can

be caused by the different ingredients in Lipexan, which, in combination with garlic, have reduced triglycerides and increased HDL.

In their study, Masoumeh Asgharpour and his colleagues examined the effect of oral consumption of garlic powder on lipid profile, inflammation and cardiovascular markers in hemodialysis patients. In this study, patients were divided into two groups and prescribed 300 mg of garlic powder or placebo for eight weeks; then the drugs were changed between the two groups; So that the group that received garlic powder for the first eight weeks, received a placebo for the second eight weeks, and vice versa. Its results showed that there was no significant difference in baseline results between the garlic and placebo groups. However, a significant decrease in the absolute values of OXLDL and HCY was seen when consuming garlic [Asgharpour M et al., 2021]. In our study, these two factors were not measured, but the LDL cholesterol factor was significantly reduced. In the study of Kejori et al., the effect of garlic powder and Antom tablets (shweed, chicory, shatare and citrus family) was investigated in comparison with placebo in patients with hyperlipidemia. In line with the present study, their results showed that in the group receiving garlic, the average cholesterol level decreased by 12.1%, LDL by 17.3%, triglyceride by 6.3%, and HDL increased by 15.7%. In the group receiving Antom tablets, only a 6% decrease in triglycerides was statistically significant. No significant results were observed in the placebo group. Garlic and dill are among the ingredients in Lipexan herbal capsules, and in the current study, significant changes in lipid profile were seen in people consuming this medicine [Kojuri J et al., 2007]. In a randomized clinical trial study, Jafarian et al investigated the effect of apple cider vinegar and watercress on hyperlipidemia compared to lovastatin. This study showed that the average cholesterol reduction at the end of the second week was 16 units in the group receiving vinegar, 5 units in the group receiving water and 21 units in the group receiving lovastatin, which reached 25, 8 and 26 units, respectively, at the end of the fourth week. The average increase of HDL at the end of the second week in the three studied groups was 20, 7, and 28 units, respectively, and at the end of the fourth week, it reached 35.7, 8.4, and 36.5

units, respectively. Within four weeks, the amount of cholesterol and HDL in the three treatment groups had a significant decrease and increase, respectively, which was in line with the findings of our study, but contrary to our results, the amount of triglycerides in the groups receiving vinegar and watercress was not significant [Jaferian S et al., 2006].

CONCLUSION:

In general, the results of this study and its comparison with similar studies showed that the herbal

medicine Lipexan (combination of fenugreek, dill, garlic, sumac and vinegar) can be one of the useful and effective drugs in treating hyperlipidemia and reducing the risk of heart diseases. be raised Although similar drugs with the same compounds were not found in the studies carried out, the effects of reducing blood lipids of each of the components of this capsule have been proven in many studies. Also, in the present study, no side effects were seen in the users of this medicine. However, it is suggested to carry out longer studies with a higher statistical population to prove this hypothesis.

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