

The results of clinical study of biologically active food supplement FanDetox

SIBERIAN STATE MEDICAL UNIVERSITY

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coralclub

The study was performed at the Siberian State Medical University of the Healthcare Ministry of Russia.



This university ranks 3rd in Russia among medical universities according to the national university ranking.

It has a collective research centre and a scientific and clinical center, own clinics.

The Siberian State Medical University clinics are one of the leading multidisciplinary institutions in the Siberian Federal District and provide all types of medical care – emergency, outpatient, inpatient, and high-tech, 20 thousand patients receive care annually.



The trial objective:

to evaluate the efficacy of the biologically active supplement FanDetox as a source of organic compounds in liver disorders.



The study was performed in accordance with the rules of Good Clinical Practice (GCP) in the Russian Federation approved by Order of the Healthcare Ministry of the Russian Federation No. 200H dated April 01, 2016, On Approval of Good Clinical Practice, Constitution of the Russian Federation, Federal Law of the Russian Federation No. 323-Φ3 dated November 21, 2011, On the Basics of Public Health Protection in the Russian Federation.

Study design:

Randomized open comparative parallel-arm study
versus standard therapy

Biologically active supplement: FanDetox;

Placebo: not used

Standard therapy: drug Carsil Forte

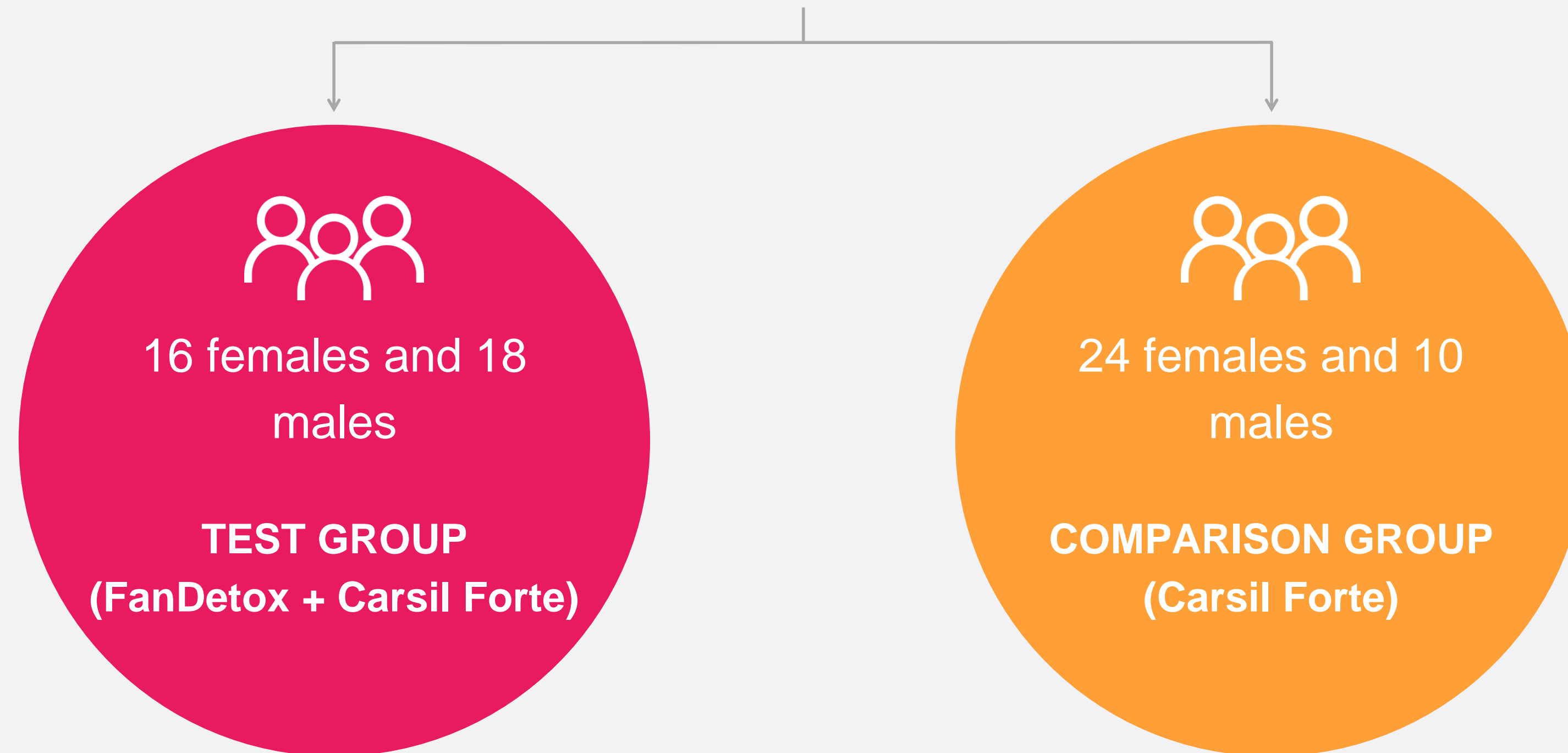
Study period: 3 months



Test group:

The study included 68 persons aged 18 to 75 years with a verified diagnosis of obesity and steatohepatosis signs.

There were 2 groups of 34 patients under study.



Hepatoses are liver diseases based on metabolic disorders in liver cells (hepatocytes) and the development of dystrophic changes in liver cells.







Dystrophy is characterized by cell damage, as a result of which the function of the organ changes.

Steatohepatosis (or fatty hepatosis) is the most common hepatosis, in which fat accumulation occurs in liver cells, and the process of their synthesis and utilization is disrupted.

Test product

FanDetox – the product developed by Korean scientist Song Hae Bok to restore and protect the liver from the toxic effects of substandard food, alcohol, drugs, and other harmful substances.

Effects claimed by the manufacturer:

-  Detoxification of the liver
-  Improved resistance to various liver diseases
-  Strengthening the function of the healthy liver
-  Beautiful skin
-  Prevention of liver cirrhosis and fatty liver disease
-  Anti-hangover agent

Test product

FanDetox will help with various problems: -

- well-being improvement with hepatitis, fatty hepatosis, etc.;
- in case of poisoning, the product actively breaks down toxic products in hepatocytes;
- it improves fat metabolism by lowering cholesterol levels in the blood;
- relieves hangover effect and all unpleasant symptoms thereof: general weakness, headache, dizziness, nausea, tremor, tachycardia, sweating, insomnia.

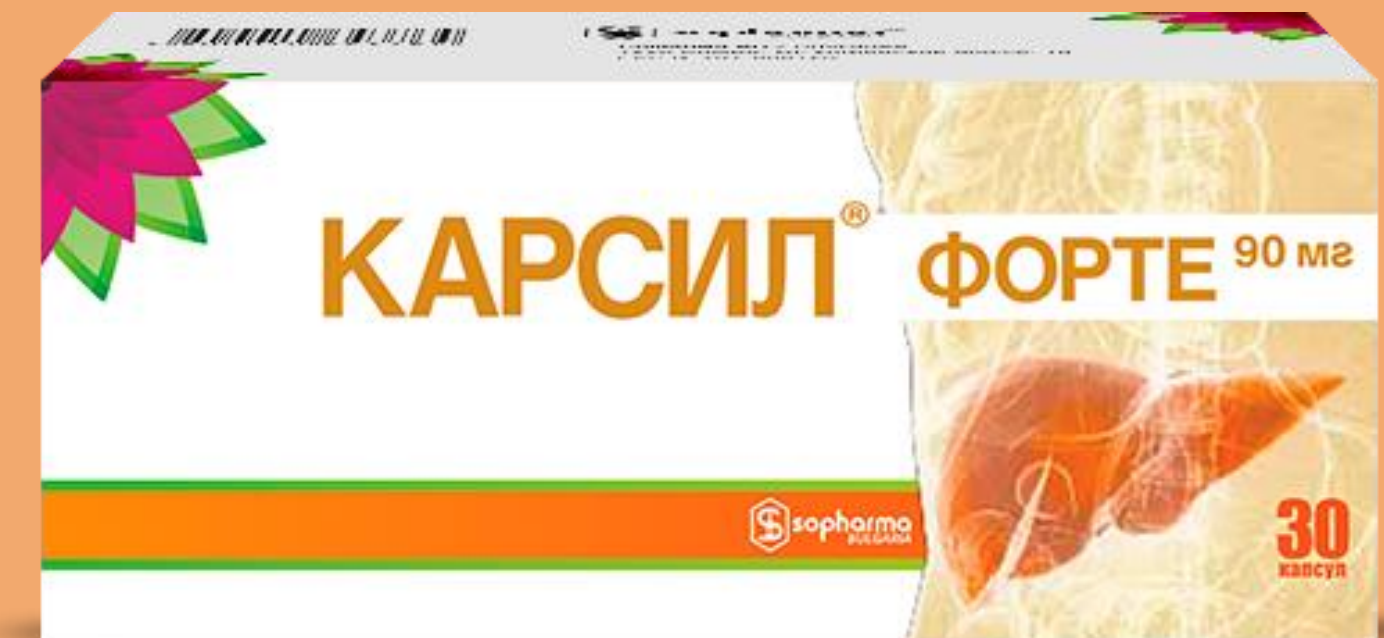
Active ingredients: glucose, persimmon fruit extract, goji berry extract, citrus peel extract, common buckwheat extract, soy sprout extract, taurine, ascorbic acid



Blank drug for both groups

Carsil Forte is a medicinal product with hepatoprotective and antioxidant effects.

The active component of the product – silymarin from *Silybum marianum* extract stimulates regeneration processes in the liver, and restores damaged liver cells (hepatocytes).



Active ingredients:

silymarin from *Silybum marianum* fruit extract

The relevance of FanDetox taking

Non-alcoholic fatty liver disease occupies a significant place in the structure of gastrointestinal tract morbidity.

Its incidence is about 20-40% according to literary sources.

Recently, the scientific literature has been actively discussing the growth of this disease.

Over the past 20 years, the number of patients with steatohepatosis has increased by 2 times.

The main causes of the development of non-alcoholic fatty liver disease are obesity, unhealthy life, cholesterol, diabetes mellitus, and genetic predisposition.



One of the possible methods of treatment may be the use of complex therapy with BAS with food.

Gerber L, Otgonsuren M, Mishra A, Escheik C, Birerdinc A, Stepanova M, et al. Non-alcoholic fatty liver disease (NAFLD) is associated with low level of physical activity: a population-based study.

Aliment Pharmacol Ther 2012; 36:772-781

Machado MV, Cortez-Pinto H. Non-invasive diagnosis of non-alcoholic fatty liver disease. A critical appraisal. J Hepatol 2013; 58:1007-1019

Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008; 336:924-926

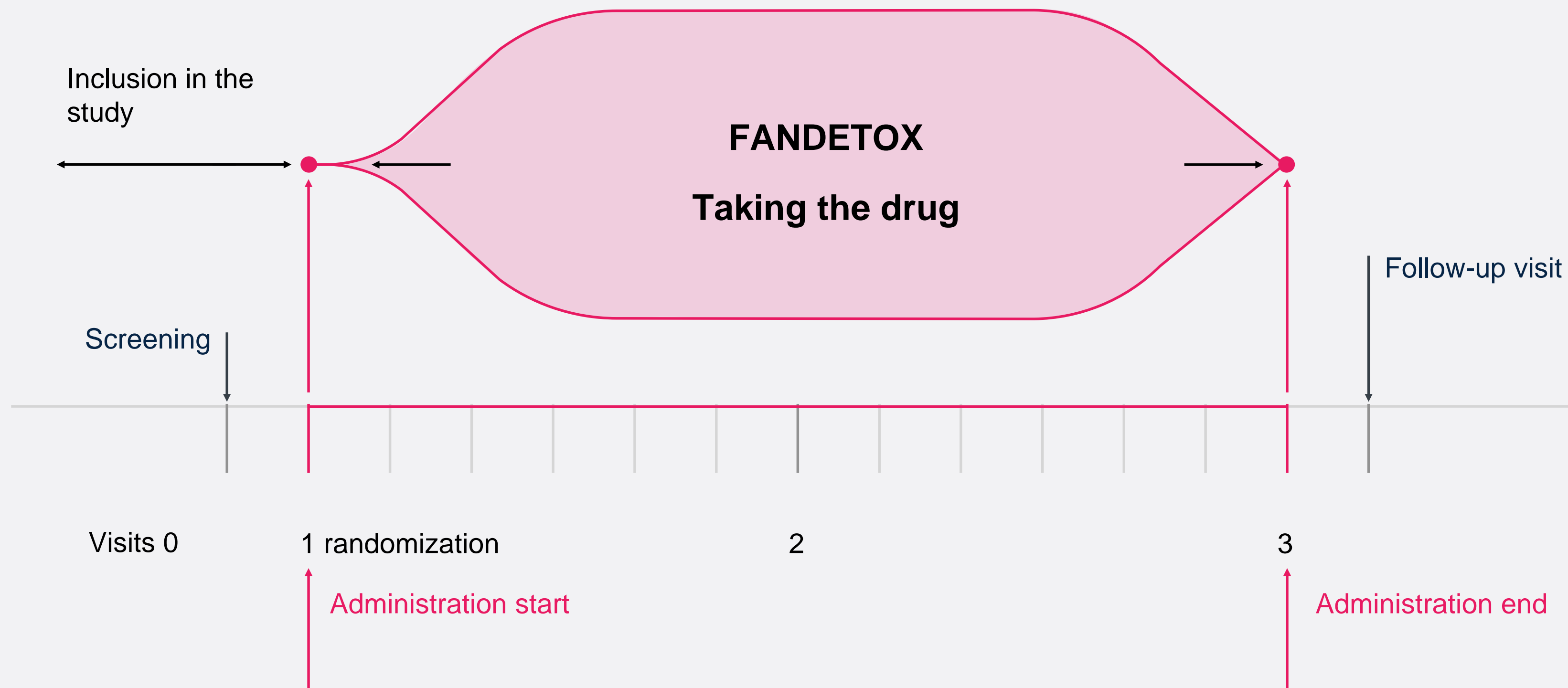
Ratziu V, Bellentani S, Cortez-Pinto H, Day C, Marchesini G. A position statement on NAFLD/NASH based on the EASL 2009 special conference. J Hepatol 2010; 53:372-384

Saadeh S, Younossi ZM, Remer EM, Gramlich T, Ong JP, Hurley M, et al. The utility of radiological imaging in nonalcoholic fatty liver disease. Gastroenterology 2002; 123:745-750

Anstee QM, Targher G, Day CP. Progression of NAFLD to diabetes mellitus, cardiovascular disease or cirrhosis. Nat Rev Gastroenterol Hepatol 2013; 10:330-344



The study design flow



Thus, the study consisted of **4 stages**:

- Screening
- Visit 1
- Visit 2
- Visit 3

The duration of therapy for each study participant was 3 months.



Screening period (zero <0> visit)

History data collection, general therapeutic examination, laboratory tests (CBC, clinical urine analysis, blood biochemistry), and studies (abdominal US, ECG)

A patient who has all the inclusion criteria and the absence of all exclusion criteria is considered eligible to participate in a clinical trial.



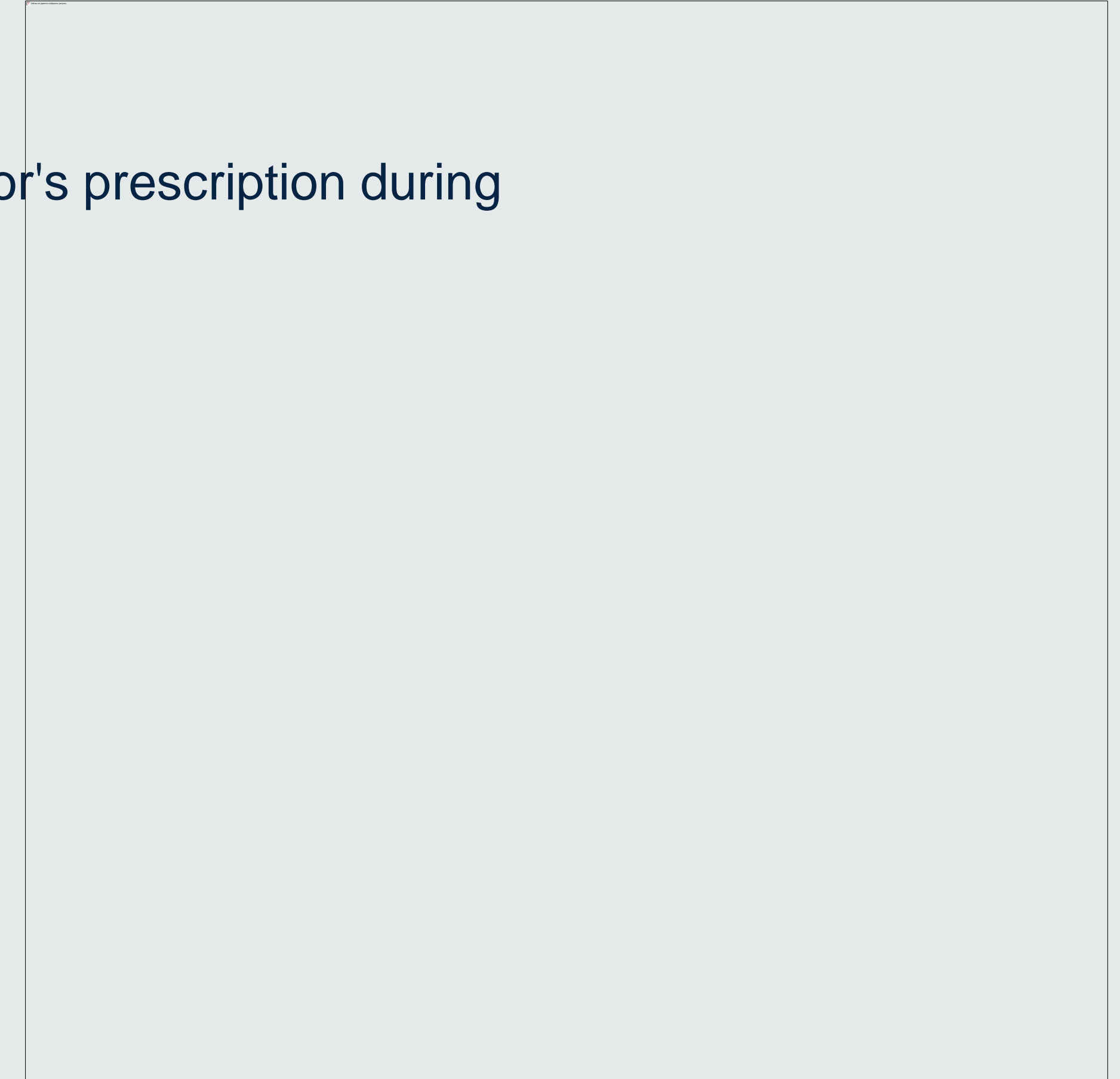


Criteria for inclusion in the study:

- men and women aged 18 to 75 years old;
- confirmed diagnosis of obesity;
- steatohepatosis signs;
- the patient's willingness not to change the prescribed therapy without a doctor's prescription during the study.

Exclusion criteria:

- carbohydrate metabolism disorders;
- treatment with any drugs that have the hepatoprotective effect;
- severe chronic diseases or clinically significant abnormalities.





Screening results

During the screening, the following deviations in indicators were revealed:

in the test group - GGTP (gamma-glutamyltranspeptidase) – 6 patients (17.6%); - increase in bilirubin – 10 patients (29.4%); - increase in AST – 7 patients (20.5%), ALT – 6 patients (17.6%); - dyslipidemia – 14 patients (41.17%).

in the comparison group

- GGTP (gamma-glutamyltranspeptidase) – 6 patients (17.6%); - increase in the level of bilirubin – 11 patients (32.3%); - increase in the level of AST – 8 patients (23.52%), ALT – 6 patients (17.6%); - dyslipidemia – 15 patients (44.11%).

- dyslipidemia – 15 patients (44.11%).

Symptoms of patients during examination: heaviness in the stomach, the right hypochondrium after meals, fatigue, complaints related to excess weight (shortness of breath when walking, sweating, joint pain).





During the initial examination, the following were revealed in the subjects:

72.3% – errors in nutrition (irregular meals, abundant food, the presence of fatty and fried foods);

46.4% – genetic predisposition to diseases of the hepatobiliary system;

37.5 % – grade I obesity;

29.7 % – grade II obesity;

26.5 % – increased body weight;

18.9% – bad habits (smoking);

6.3 % – grade III obesity;

Pathology of the gallbladder and pancreas, duodenum, gastroesophageal reflux disease (GERD) was often encountered.





Visits 1, 2, 3 to the doctor

Randomization (Visit No. 1)

History data collection, therapeutic examination (including weighing, height determination, body temperature measurement), and examination to assess inclusion and exclusion criteria.

Delivery of the test product and the control drug in the amount required for 3 months of treatment. The results of the study are recorded in an individual registration record.

Visit No. 2, visit No. 3

History data collection, assessment of undesirable symptoms, therapeutic examination Laboratory tests, and studies are performed.

The study results are registered in an individual registration record.

Visit No. 2 a month after visit No. 1

Visit No. 3 2 months after visit No. 2



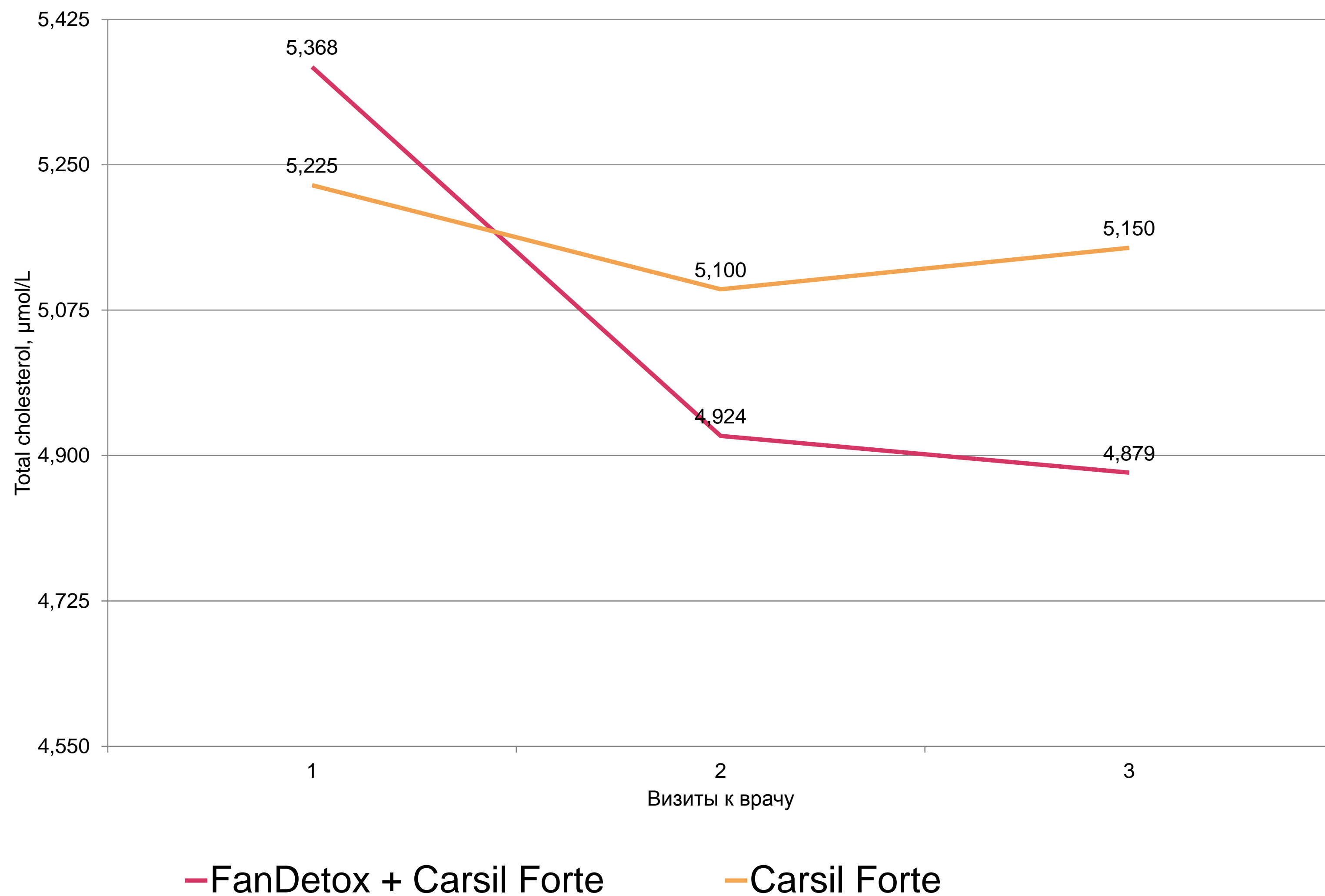
Study results

The criteria for evaluating the effectiveness of the dietary supplement FanDetox effect were the following indicators:

- total cholesterol;
- the activity of liver enzymes ALT, AST;
- atherogenic index;
- bilirubin;
- gamma-glutamyltransferase;
- oblique-vertical liver dimension;
- the general well-being of the study participants.



Changes in total cholesterol over time



Reducing total cholesterol

In the test group (FanDetox + Carsil Forte) by 8% (0.488 mmol/L)

In the comparison group (Carsil Forte) by 1% (0.075 mmol/L)

- **Cholesterol is the main steroid in the human body.**

It is a vital lipid involved in hormone synthesis, and digestive processes and is part of cell membranes.

Elevated cholesterol plays a leading role in the development of cardiovascular diseases, and cholelithiasis, and also increases the risk of pancreatitis.

- **One of the main conditions for normal cholesterol metabolism is effective liver functioning.**

With normal liver function, the content of useful cholesterol (high-density lipoproteins) is greater than low-density lipoproteins. With an increased level of low-density lipoproteins, the process of atherosclerotic plaque formation is triggered.

- **Dyslipidemia** is a violation of high-density lipoproteins and low-density lipoproteins balance.

Liver enzyme activity

ALT and AST are liver enzymes involved in protein metabolism. They are found in large quantities in the liver, kidneys, heart muscle, and skeletal muscles, and changes in their concentration in the blood are more often associated with liver diseases.

A high indicator of ALT and AST enzymes is a blood level above 25 U/L.

| TEST GROUP (FanDetox + Carsil Forte): Decrease in blood liver enzymes, U/L | AST | ALT | COMPARISON GROUP (Carsil Forte): Decrease in blood liver enzymes, U/L | AST | ALT |
|--|---------------|---------------|---|--------------|--------------|
| Mean | -32.3% | -35.2% | Mean | -0.9% | -7.0% |

Atherogenic index

Atherogenic index (AI) is a biochemical indicator that shows the ratio of bad and good cholesterol. The index helps to assess the likelihood of developing atherosclerosis, and cardiovascular pathologies, and to track the effectiveness of preventive measures in persons from risk groups.

The atherogenic index equal to 2-3 is considered optimal.

Reduction of the atherogenic index:

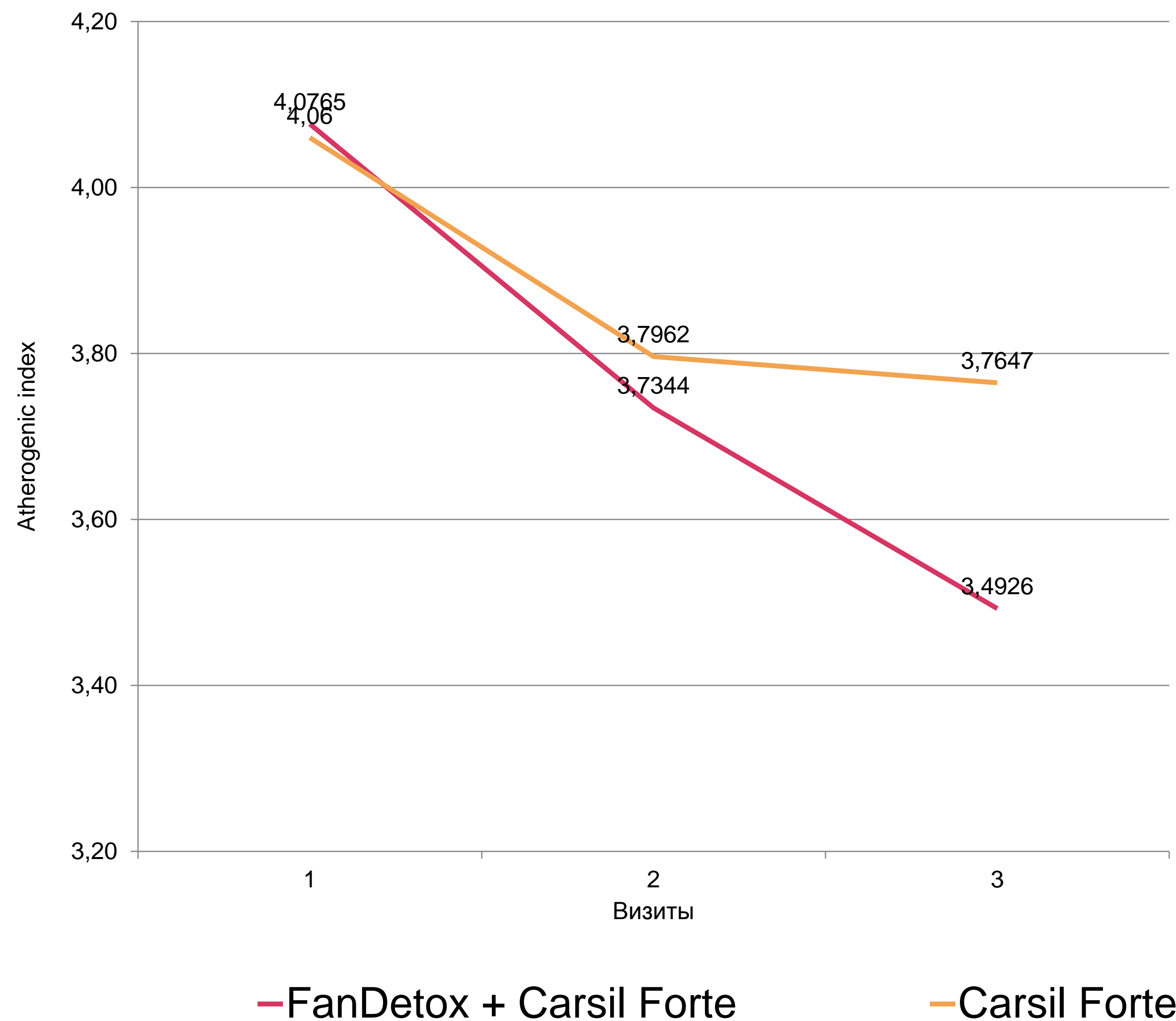
14.5%

in the test group (**FanDetox + Carsil Forte**)
by about 14.5%

7.4%

in the comparison group (**Carsil Forte**) by about 7.4%

Changes in the atherogenic index over time



Reduction of the atherogenic index

In the test group (FanDetox + Carsil Forte) – by 14.5%

In the comparison group (Carsil Forte) – by 7.4%

Total bilirubin

Bilirubin is a pigment formed during the breakdown of hemoglobin and some other heme-containing proteins in the liver, spleen, and bone marrow.

It exhibits toxicity to the nervous system and must be removed from the body with bile or urine. Bilirubin excretion is a multi-stage process in which the liver plays a major role. An increase in bilirubin can be observed in liver diseases.

Total bilirubin standard is 3.4-17.1 mmol/L.

Reducing total bilirubin:

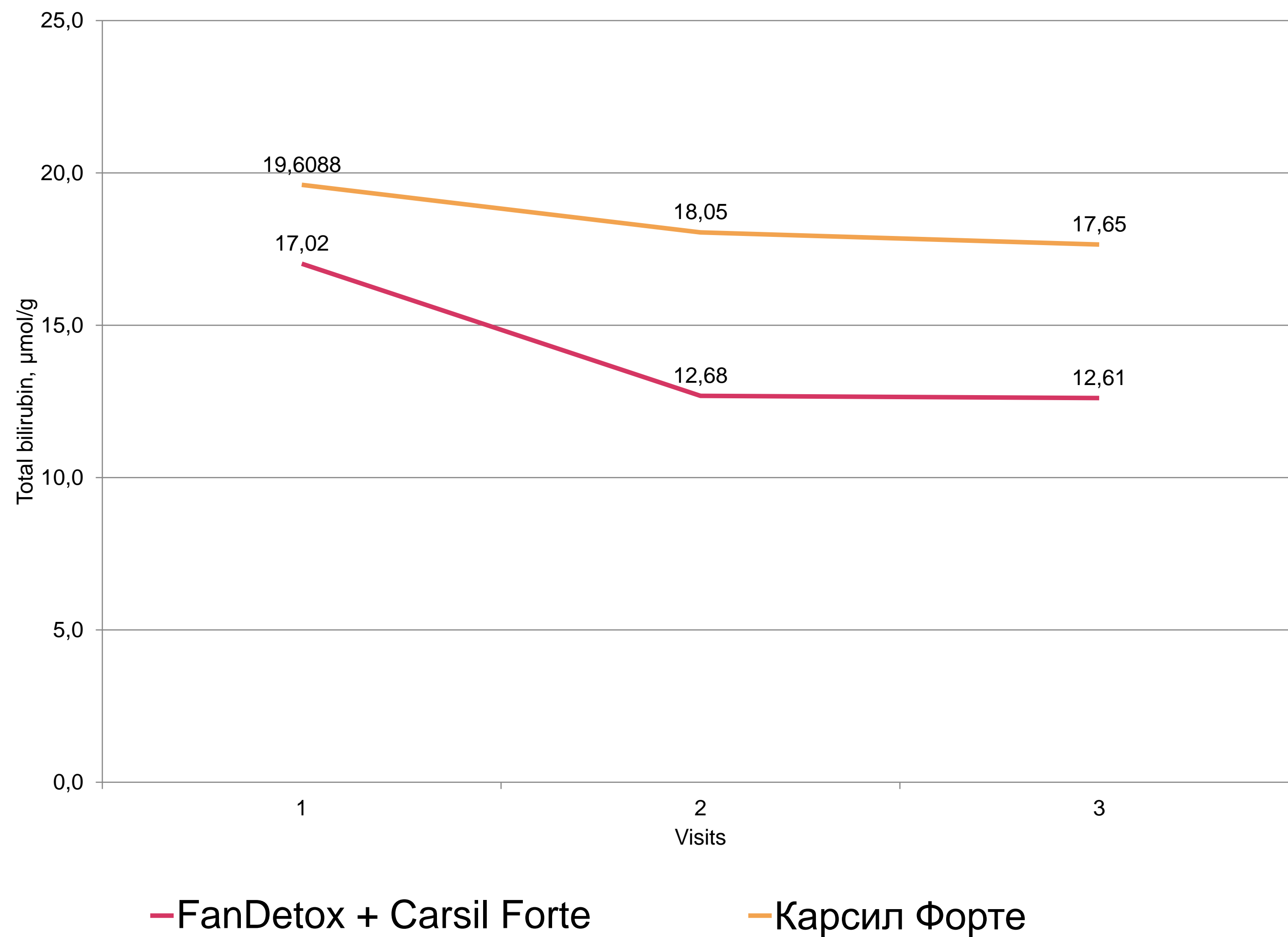
25.8%

in the test group (**FanDetox + Carsil Forte**) by about 25.8%

10%

in the comparison group (**Carsil Forte**) by about 10%

Changes in total bilirubin over time



Reducing total bilirubin

In the test group (FanDetox + Carsil Forte) by 25.8% (4.39 $\mu\text{mol/L}$)

In the comparison group (Carsil Forte) – by 10% (1.96 $\mu\text{mol/L}$)

GGTP

Gamma-glutamyltranspeptidase (gamma-GT) is an enzyme that reflects the state of the liver and biliary tract tissues. Currently, gamma-GT is the most sensitive marker of liver diseases. An increase in the concentration of gamma-GT can be observed in all liver diseases, but this indicator is of the greatest importance for the diagnosis of biliary tract obstruction.

Reference interval: women over 18 years old < 38 U/L, men over 18 years old < 55 U/L

Reduction of GGTP:

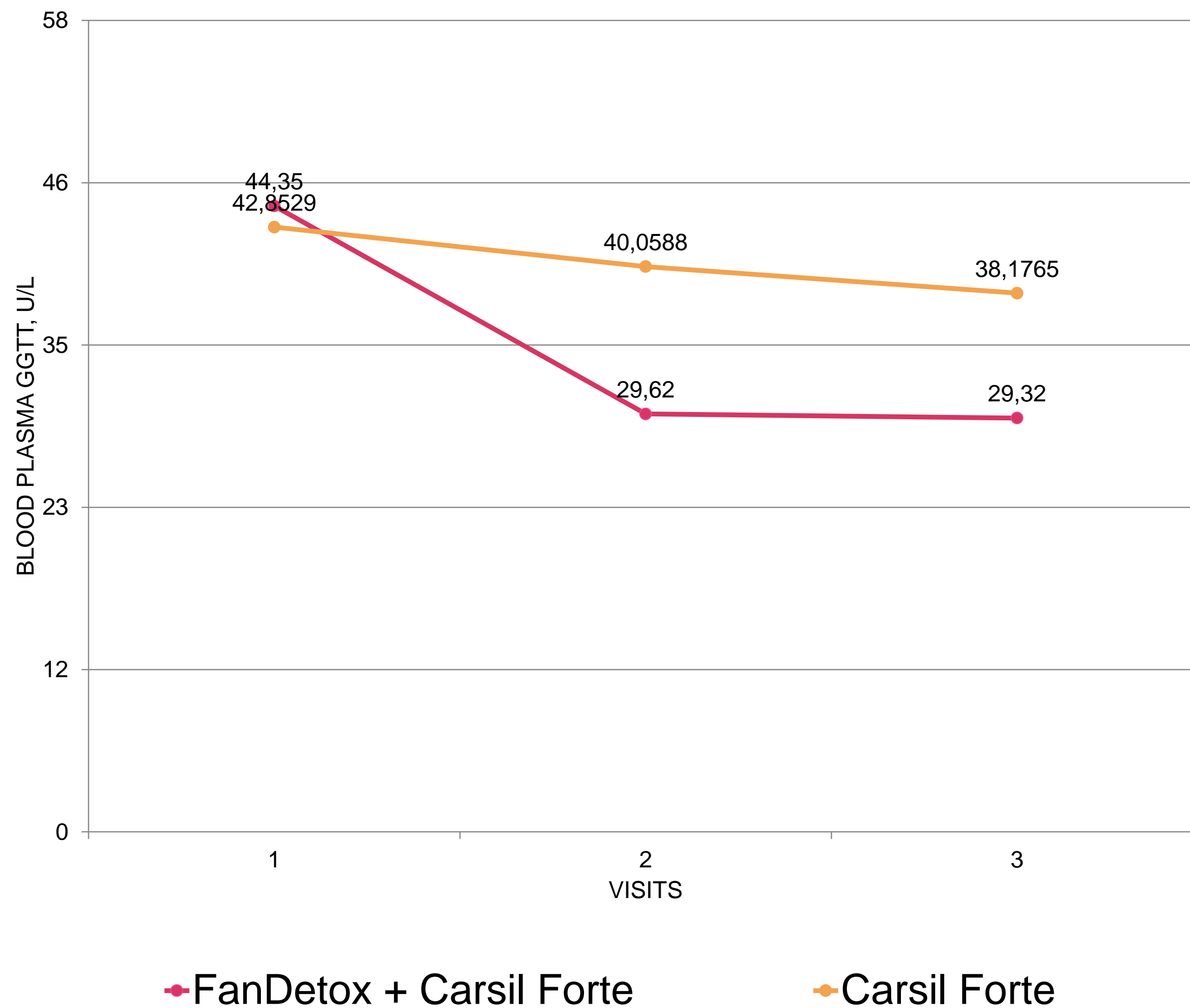
33.3%

in the test group (**FanDetox + Carsil Forte**) by about 33.3%

10.9%

in the comparison group (**Carsil Forte**) by about 10.9%

Changes in GGTP enzyme over time

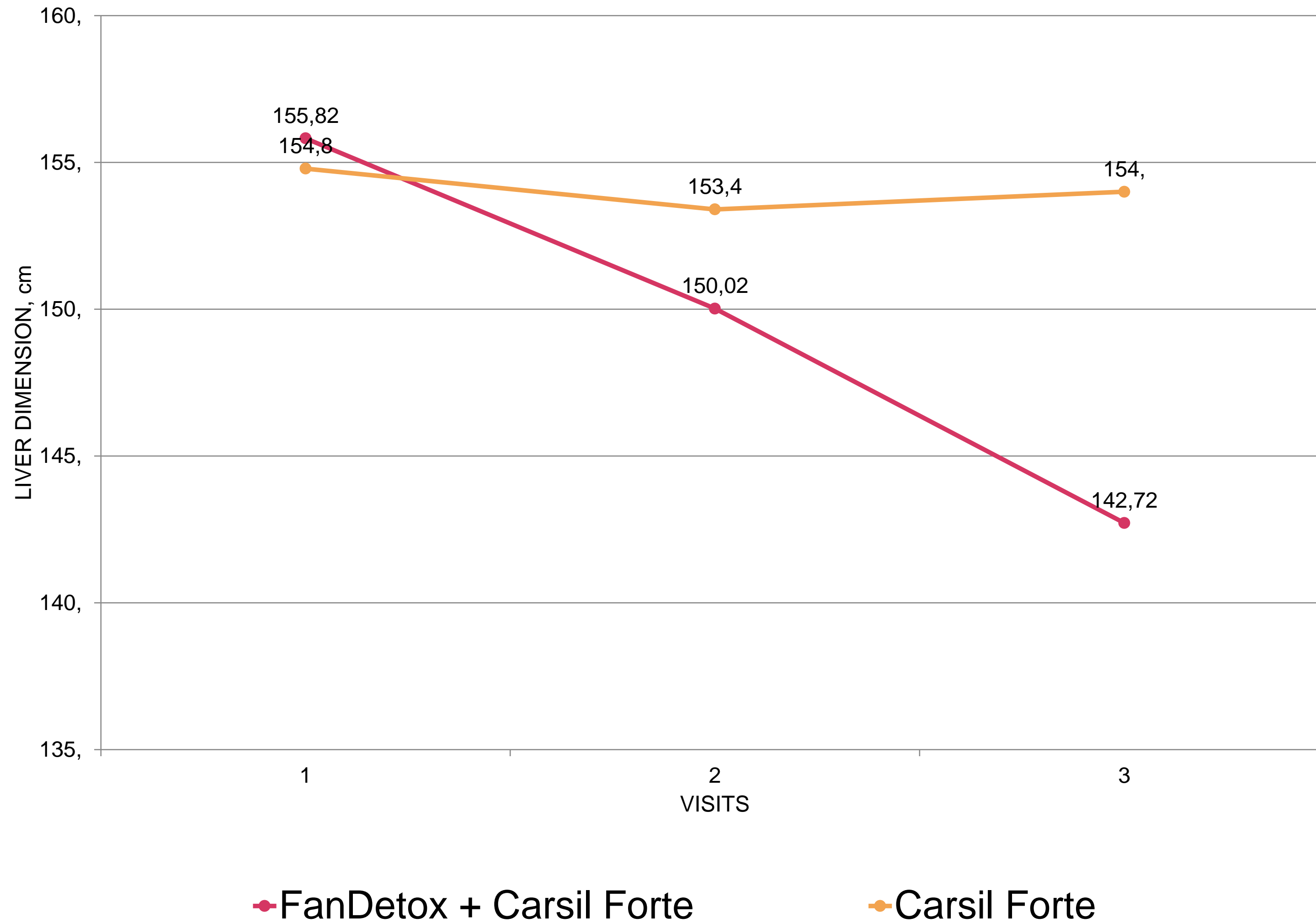


Reduction of GGTP enzyme in blood plasma

In the test group (FanDetox + Carsil Forte) – by 33.3% (14.68 U/L)

In the comparison group (Carsil Forte) – by 10.9% (4.67 U/L)

Oblique-vertical liver dimension



There is a positive dynamics of the liver oblique-vertical dimension from 155.82 to 142.72 in the test group, while in the comparison group the dynamics from 154.79 to 154 were not significant.

Study results: general well-being of the participants

- The study participants noted an improvement in well-being on average 7-10 days after the start of taking FanDetox + Carsil Forte.
- Most of the patients noted a decrease in the severity of GERD symptoms and normalization of appetite.

Nausea, flatulence, and gastrointestinal pain decreased.



| Symptoms | Test group (FanDetox + Carsil Forte) (n = 34) | | Comparison group (Carsil Forte) (n = 34) | |
|----------------------------|---|---------------------|--|---------------------|
| | Before treatment (%) | After treatment (%) | Before treatment (%) | After treatment (%) |
| Language plaque | 29.8 | 27.7 | 30.3 | 28.1 |
| Tenderness under palpation | 33.3 | 17.5 | 36.9 | 34.3 |
| Right hypochondrium | 15.8 | 12.3 | 17.2 | 15.6 |
| Epigastric region | 14.5 | 12.3 | 12.5 | 10.6 |
| Left hypochondrium | 13.3 | 12.6 | 12.6 | 10.8 |
| Umbilical region | 15.8 | 13.8 | 19.7 | 16.1 |
| Gallbladder symptoms (+) | 73.7 | 41.5 | 75.3 | 49.9 |

During the therapy, improvement was noted in the participants of the groups during an objective examination:

reduction of soreness in the right hypochondrium, and stomach;

reduction of gallbladder symptoms severity.

Conclusions based on the results of the clinical study of the complex application of dietary supplement FanDetox and the drug Carsil Forte

- The inclusion of the biologically active supplement FanDetox in complex therapy for fatty liver disease, dyslipidemia, and obesity is evidence-based.
- As part of complex therapy, the biologically active additive FanDetox shows more effective results in reducing total cholesterol, bilirubin, atherogenic index, liver enzymes ALT and AST, and GGTP in blood plasma.
- The inclusion of the biologically active supplement FanDetox in complex therapy improves the subjective well-being status of patients with fatty liver disease, dyslipidemia, and obesity.
- The inclusion of the biologically active supplement FanDetox in complex therapy leads to a more effective reduction in the longitudinal liver dimension according to ultrasound control.

Conclusion

- Biologically active supplement FanDetox is recommended to be included in the complex therapy of patients with fatty liver disease, obesity, and dyslipidemia.
- There were no adverse events associated with taking the biologically active supplement; the tolerability of the food supplement FanDetox was good.

Thank you
for attention!



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