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Autoprobiotic Enterococcus supplements for the treatment of metabolic syndrome

Submission date
04/06/2026

Recruitment status
No longer recruiting

Registration date
05/06/2026

Overall study status
Completed

Last Edited
05/06/2026

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aim
Metabolic syndrome (MetS) is a cluster of conditions – including excess abdominal fat, high blood sugar, abnormal cholesterol levels, and high blood pressure – that occur together and increase the risk of heart disease, stroke, and type 2 diabetes. Research shows that the bacteria living in the gut (gut microbiota) play an important role in metabolic health.
This study tests a new, personalised approach called "autoprobiotics". Unlike standard probiotics that come from a common bacterial product, autoprobiotics are made from a person's own gut bacteria (Enterococcus species), which are isolated, grown in the laboratory, and given back to the same individual. This study aimed to find out whether taking autoprobiotic supplements for 20 days can reduce body weight, improve blood sugar, improve cholesterol levels, and beneficially change the gut microbiota in people with MetS.

Who can participate?
Patients aged 25 to 75 years (men and women) with a diagnosis of metabolic syndrome.

What does the study involve?
People who joined the study were each given a unique ID number and randomly assigned to one of two groups by a researcher who was not involved in the study and did not know who the participants were. Neither the participants nor the study team knew which treatment anyone was receiving during the study.

Intervention (Autoprobiotic group)
For those in the autoprobiotic group, a sample of their stool was used to isolate naturally occurring, harmless bacteria (Enterococcus species) from their own gut. These bacteria were grown in the laboratory to make a personalised product.
This product contained a specific amount of these bacteria (5×10^8 CFU per mL) and was taken by mouth as a liquid. Participants drank 50 mL twice a day for 20 days, from Day 15 to Day 34 of the study.

Control (Placebo group)
Participants in the control group received a placebo liquid that looked and tasted the same as the autoprobiotic product but did not contain any live bacteria.

They took the same amount (50 mL twice a day by mouth) for the same 20-day period (Day 15 to Day 34).

What are the possible benefits and risks of participating?
Benefits and risks not provided at time of registration

Where is the study run from?
Institute of Experimental Medicine, Saint-Petersburg, Russian federation.

When is the study starting and how long is it expected to run for?
May 2023 to January 2026

Who is funding the study?
Ministry of Science and Higher Education of the Russian Federation.

Who is the main contact?
Prof Elena Ermolenko, Lermolenko1@yandex.ru

Contact information

Type(s)
Principal investigator, Public, Scientific

Contact name
Prof Elena Ermolenko

ORCID ID
https://orcid.org/0000-0002-2569-6660

Contact details
Saint-Petersburg, acad. Pavlov str., 12
Saint-Petersburg
Russian Federation
197376
+7(812) 2340542
Lermolenko1@yandex.ru

Additional identifiers

The Ministry of Science and Higher Education of the Russian Federation (State Assignment) Grant /Reference: State Assignment No.
075-00397-25-03 (1022041101032-1-1.6.2; FGWG-2025-0010)

Study information

Scientific Title
In patients with metabolic syndrome (Participants), do autoprobiotic supplements based on indigenous non-pathogenic Enterococcus faecium and Enterococcus hirae strains (Intervention),

compared to placebo (Comparison), improve anthropometric parameters, carbohydrate and lipid metabolism, and gut microbiota composition (Outcomes): a pilot randomized, placebo-controlled trial (APMETS-Pilot)

Acronym
APMETS-Pilot

Study objectives
To evaluate the effectiveness of autoprobiotic treatment using indigenous non-pathogenic Enterococcus faecium and Enterococcus hirae strains on anthropometric parameters (body weight, BMI, waist circumference, hip circumference, waist-to-hip ratio) in patients with metabolic syndrome.
To assess the effect of autoprobiotic treatment on carbohydrate metabolism (fasting serum glucose) in patients with metabolic syndrome.
To assess the effect of autoprobiotic treatment on lipid profile parameters (total cholesterol, triglycerides, HDL, LDL, VLDL, non-HDL cholesterol, atherogenicity coefficient) in patients with metabolic syndrome.
To evaluate changes in gut microbiota composition (quantitative and qualitative) following autoprobiotic treatment, using qPCR and 16S rRNA gene sequencing.
To assess the safety and tolerability of autoprobiotic Enterococcus strains in patients with metabolic syndrome.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/05/2023, Local Ethics Committee of Almazov National Medical Research Centre (197341, St. Petersburg, 2 Akkuratova Street, St. Petersburg, 197341, Russian Federation; +7 (812) 7023749; lec@almazovcentre.ru), ref: 05-23

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied

Metabolic syndrome (MetS); obesity; dyslipidaemia (hyperlipidaemia types of IIa and IIb by Fredrickson classification); impaired glucose tolerance

Interventions

Randomization was based on a pre-computer-generated random assignment sequence using the block method; distribution concealment was ensured using sequentially numbered opaque sealed envelopes.

At enrollment, eligible participants were assigned a unique identification number and were randomized (1:1) (https://www.randomizer.org) to one of the treatment groups. Randomization was performed by an investigator who was not involved in participant recruitment, clinical assessment, or outcome assessment, and who did not know the names of participants. This researcher kept a list of unique identification numbers and intervention assignment information in a sealed envelope in a secure location. The study product and placebo were packaged identically and were dispensed without any indication of group allocation on the label. All investigators, study coordinators, and participants were blinded to group assignment throughout the study. Group allocation information was disclosed after completion of data collection, database locking, and final approval of the statistical analysis plan, immediately before the final statistical analysis was performed.

Experimental Group (Ap; n = 25) – Autoprobiotic:
Non-pathogenic, indigenous Enterococcus faecium or Enterococcus hirae strains isolated from each participant's own fecal sample are grown to prepare a personalised functional food product (PFFP). The finished autoprobiotic product contains 5×10^8 CFU/mL of the indigenous Enterococcus strain and is administered at a dose of 50 mL twice daily by mouth for 20 days (Days 15–34 of the protocol).

Control Group (Pl; n = 25) – Placebo:
Participants receive SuproPlus 2640 (Monsanto Company, MO, USA; 40 g/L nutrient medium) – the same medium used as the base for autoprobiotic cultivation – without viable autoprobiotic bacteria, administered at the same volume (50 mL twice daily by mouth) for 20 days (Days 15–34).

Intervention Type

Supplement

Primary outcome(s)

1. Body weight (BW) in kilograms measured using medical scales (Massa-VEM-150, Massa-K, St. Petersburg, Russia) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

2. Body mass index (BMI) measured using standard procedures to calculate BW (kg) / height (m^2) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

3. Waist circumference (WC) in centimetres measured using standard procedures at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

4. Fasting serum glucose in mmol/L measured using an automated biochemical analyser (Abbott ARCHITECT ci8200) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

Key secondary outcome(s))

1. Hip circumference (HC) in centimetres measured using standard procedures at baseline (day 0 /V1), day 49 (V2), and day 64 (V3)

2. Waist-to-hip ratio (WHR) measured using standard procedures to calculate waist circumference (cm) divided by hip circumference (cm) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

3. Serum total cholesterol in mmol/L measured using an automated biochemical analyser (Abbott ARCHITECT ci8200) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

4. Serum triglycerides (TG) in mmol/L measured using an automated biochemical analyser (Abbott ARCHITECT ci8200) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

5. Serum HDL cholesterol in mmol/L measured using an automated biochemical analyser (Abbott ARCHITECT ci8200) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

6. Serum LDL cholesterol in mmol/L measured using an automated biochemical analyser (Abbott ARCHITECT ci8200) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

7. Serum VLDL cholesterol in mmol/L measured using an automated biochemical analyser (Abbott ARCHITECT ci8200) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

8. Atherogenicity coefficient measured using collected data to calculate the lipid profile using the standard formula: (total cholesterol – HDL cholesterol) / HDL cholesterol at baseline (day 0 /V1), day 49 (V2), and day 64 (V3)

9. Quantitative assessment of gut microbiota measured using qPCR using Colonoflor 16 Premium kit (log_{10} copies/g feces) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

10. Gut microbiota composition (taxonomic profile) measured using 16S rRNA gene sequencing (V3–V4 hypervariable regions; MiSeq platform, Illumina) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

11. Gastrointestinal symptom severity measured using a study-specific gastroenterological questionnaire (assessing abdominal pain, flatulence, nausea, stool frequency, Bristol stool scale) at baseline (day 0/V1), day 49 (V2), and day 64 (V3)

12. Safety and tolerability throughout the study period (Days 0–64) measured using data collected on the incidence and nature of adverse events, accessed at continuous time points

Completion date
12/01/2026

Eligibility

Key inclusion criteria
1. Diagnosis of metabolic syndrome
2. Age 25 to 75 years (men and women)
3. Overweight or abdominal obesity: BMI > 25 kg/m² AND waist circumference ≥ 94 cm in men or ≥ 80 cm in women
4. Altered lipid profile consistent with hyperlipidemia types of IIa or IIb (Fredrickson

classification)
5. Disorder of carbohydrate metabolism presenting as impaired glucose tolerance
6. Signed voluntary informed consent
7. Lower age limit: 25 years
8. Upper age limit: 75 years
9. Sex: Both male and female (sex-matched allocation between groups)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
25 years

Upper age limit
75 years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Concomitant diseases requiring constant or long-term therapy that could affect study results
2. Cancer or myeloproliferative diseases
3. Substance or alcohol abuse
4. Current pregnancy or at the stage of pregnancy planning
5. Current use of antibacterial, antiviral, antifungal, or antiprotozoal drugs
6. Use of laxatives, cleansing enemas, probiotics, or dietary supplements within 14 days prior to enrolment (wash-out required). If the patient needed to change therapy (or it was recently changed), if there were recent lifestyle changes (nutrition, physical activity), then the patient's inclusion was postponed until stabilization for 2-4 weeks. The conditions for inclusion in the study were stable therapy, a stable diet, and a stable level of physical activity.
7. Use of lactic acid products within 14 days prior to enrolment

Date of first enrolment
15/05/2023

Date of final enrolment
03/11/2025

Locations

Countries of recruitment
Russian Federation

Sponsor information

Organisation
Institute of Experimental Medicine

ROR
https://ror.org/0344x6030

Organisation
The Ministry of Education and Science of the Russian Federation

ROR
https://ror.org/00ghqgy32

Funder(s)

Funder type

Funder Name
Ministry of Science and Higher Education of the Russian Federation

Alternative Name(s)
МИНИСТЕРСТВО НАУКИ И ВЫСШЕГО ОБРАЗОВАНИЯ РОССИЙСКОЙ ФЕДЕРАЦИИ, Ministry of Science and Higher Education (Russia), Ministry of Science and Higher Education, Федеральная целевая программа, Ministry of Science and Higher Education, Russia, Minobrnauki of Russia

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Russian Federation

Results and Publications

Individual participant data (IPD) sharing plan
The data that support the findings of this study are available from the corresponding author (Prof. Elena Ermolenko) upon reasonable request. No formal data repository submission is indicated in the published manuscript.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			05/06/2026	No	No
Other files			05/06/2026	No	No
Other files			05/06/2026	No	No
Other files			05/06/2026	No	No
Participant information sheet	version 1.0	24/04/2023	05/06/2026	No	Yes