

Probiotics for men

Submission date 03/07/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/07/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/01/2025	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The microbiota of the male genital tract plays an important role in men's health. It affects semen quality and prostate health. Prostatitis syndrome is associated with microbiota imbalance in the male genital organs. Various animal experiments have proven that probiotics can improve sperm quality or influence testosterone levels. Scarce studies have shown a beneficial effect of probiotics in the case of prostatitis. The study team developed a probiotic mixture for prostatitis patients using laboratory experiments. As a next step, the safety and tolerability of this novel probiotic mixture will be tested in healthy volunteers.

Who can participate?

Healthy volunteer men aged between 18-65 years old

What does the study involve?

Study participants consume 1 oral capsule per day containing four lactobacilli strains (daily dose 10E9 CFU) for one week. Blood markers are recorded at the beginning and at the end of the study. The participants fill out a daily questionnaire during the consumption period about their health and well-being.

What are the possible benefits and risks of participating?

A possible benefit is proving the safety of potential probiotics in healthy men. Possible risks are low since the European Food Safety Association (EFSA) has placed lactobacilli on the qualified presumption of safety (QPS) list. In addition, the study team tested several safety markers in the lactobacilli strains in the laboratory.

Where is the study run from?

University of Tartu (Estonia)

When is the study starting and how long is it expected to run for?

December 2020 to December 2022

Who is funding the study?

Competence Centre on Health Technologies (Estonia)

Who is the main contact?

Dr Reet Mändar, reet.mandar@ut.ee (Estonia)

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Safety of potential probiotics in healthy male volunteers

Study objectives

Novel probiotic mixture is safe and well tolerable during oral consumption.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 19/09/2022, Research Ethics Committee of the University of Tartu (Raekoja plats 9, Tartu, 51004, Estonia; +372 737 6215; eetikakomitee@ut.ee), ref: 368/M-5

Study design

Interventional non-randomized study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other therapist office

Study type(s)

Safety

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Safety of potential probiotics in healthy male volunteers

Interventions

Healthy volunteer men aged 18-65 without health complaints are recruited. The research material is probiotic capsules used as a food supplement, which contain 4 different strains of lactobacilli with a total germ count of 10^9 microbial cells. Probiotic bacteria are lyophilized and packaged in capsules. Based on in vitro tests, the strains selected for the study prevent the growth of bacteria associated with genitourinary tract infections, and their antibiotic sensitivity profile meets the requirements of the European Food Safety Authority. Study participants consume 1 capsule per day (daily dose of probiotic microbe: 10^9 CFU) for one week. Blood markers (haemoglobin (g/L), haematocrit (%), WBC (10^9 /L), RBC (10^{12} /L), platelets (10^9 /L), neutrophils (10^9 /L), eosinophils (10^9 /L), basophils (10^9 /L), monocytes (10^9 /L), lymphocytes (10^9 /L), Ig (%), CRP (mg/L), HbA1c (mmol/mol), glucose (mmol/L), cholesterol (mmol/L), LDL (mmol/L), HDL (mmol/L), GGT (U/L), ALAT (U/L), ASAT (U/L), creatinin (μ mol/L), EGFR (mL/min/1.73m²), estradiol (pmol/L), testosterone (nmol/L), SHBG (nmol/L), FAI (%), and PSA (μ g/L)) are recorded at the beginning and at the end of the study. The participants fill out a short daily questionnaire during the consumption period about their health and well-being.

Intervention Type

Supplement

Primary outcome measure

Safety and tolerability of the probiotic capsules measured using a bespoke daily questionnaire at baseline and one week at the end of the study

Secondary outcome measures

Levels of blood markers measured using blood analysis and general health conditions measured using a questionnaire are assessed before and at the end of the study (one week later)

Overall study start date

02/12/2020

Completion date

31/12/2022

Eligibility

Key inclusion criteria

Healthy volunteer men aged 18-65 years without health complaints

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Male

Target number of participants

10

Total final enrolment

10

Key exclusion criteria

1. Inflammation of the urogenital tract
2. Diabetes
3. Acute/chronic (infectious) disease
4. Cardiovascular disease
5. Food allergy
6. Use of antibiotics within 4 weeks before the study
7. Regular use of NSAID
8. Blood donation within the last month

Date of first enrolment

22/09/2022

Date of final enrolment

20/12/2022

Locations**Countries of recruitment**

Estonia

Study participating centre

MediTA Clinic

Teguri 37b

Tartu

Estonia

51013

Sponsor information**Organisation**

Competence Centre on Health Technologies (Estonia)

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.ccht.ee>

ROR

<https://ror.org/05kagrs11>

Funder(s)

Funder type

Research organisation

Funder Name

Competence Centre on Health Technologies (CCHT)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

The datasets generated during the study will be available upon reasonable request from Dr Reet Mändar, reet.mandar@ut.ee

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Safety investigation of potential probiotics in healthy volunteers in men		05/07/2023	No	No

Participant information sheet	Subject information and informed consent form [Estonian]	05/07/2023	No	Yes	
Results article		04/01/2025	20/01/2025	Yes	No