ISRCTN54942056 https://doi.org/10.1186/ISRCTN54942056

Probiotics for men

Submission date 03/07/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/07/2023	**Overall study status** Completed	
Last Edited 20/01/2025	**Condition category** Other	

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
Prof Reet Mändar

ORCID ID
https://orcid.org/0000-0002-9747-3618

Contact details
University of Tartu
Ravila 19
Tartu
Estonia
50411
+372 7 374 179
reet.mandar@ut.ee

Type(s)
Scientific

Contact name
Dr Kristo Ausmees

Contact details
Medita clinic in Tartu
Teguri 37b
Tartu
Estonia
50107
+372 52 17501
kristo.ausmees@medita.ee

Type(s)
Public

Contact name
Ms Imbi Smidt MSc

Contact details
University of Tartu
Ravila 19
Tartu
Estonia

50411
+372 7 374 178
imbi.smidt@ut.ee

Additional identifiers

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

Primary study design
Interventional

Study design
Interventional non-randomized study

Study type(s)
Safety

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 10E9 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: 10E9 CFU) for one week. Blood markers (haemoglobin (g/L), haematocrit (%), WBC (10E9/L), RBC (10E12 /L), platelets (10E9/L), neutrophils (10E9/L), eosinophils (10E9/L), basophils (10E9/L), monocytes (10E9/L), lymphocytes (10E9/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 (µmol/L), EGFR (mL/min/1, 73m2), estradiol (pmol/L), testosterone (nmol/L), SHBG (nmol/L), FAI (%), and PSA (µg/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(s)
Safety and tolerability of the probiotic capsules measured using a bespoke daily questionnaire at baseline and one week at the end of the study

Key secondary outcome(s)
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)

Completion date
31/12/2022

Eligibility

Key inclusion criteria
Healthy volunteer men aged 18-65 years without health complaints

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Male

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)

ROR
https://ror.org/05kagrs11

Funder(s)

Funder type
Research organisation

Funder Name
Competence Centre on Health Technologies (CCHT)

Results and Publications

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?
Results article		04/01/2025	20/01/2025	Yes	No
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