

Safety and efficacy of putative vaginal probiotics in healthy women

Submission date 11/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/04/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/05/2019	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Probiotics are beneficial microbes that survive gastrointestinal passage and may improve microbiota. Daily oral intake of probiotic *Lactobacillus crispatus* strains may increase number of lactobacilli in the gut and vaginal microbiota. The aim of the study is to assess safety and efficacy of orally administered *Lactobacillus crispatus* strains in healthy women.

Who can participate?

Healthy women between the age of 18 and 50.

What does the study involve?

Eligible participants are randomly allocated to one of four groups. They take either the probiotic or a placebo every day for a week. This is followed by a so-called “wash out” period where the participants resume their normal diet but don’t take any probiotics. After this wash out period is complete, participants who had taken the probiotic are now given the placebo for a further week and vice versa.

What are the possible benefits and risks of participating?

There are no expected risks in participating, except a small risk of bruising from giving the blood sample.

Where is the study run from?

Competence Centre on Health Technologies (Estonia)

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

March 2015 to August 2015.

Who is funding the study?

Competence Centre on Health Technologies (Estonia)

Who is the main contact?

Professor Reet Mändar
reet.mandar@ut.ee

Study website

N/A

Contact information

Type(s)

Scientific

Contact name

Prof Reet Mändar

Contact details

Tiigi 61b

Tartu

Estonia

50410

+372 7374 178

reet.mandar@ut.ee

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

244/T-14

Study information

Scientific Title

Safety and efficacy of potential vaginal probiotics administrated orally in healthy volunteers

Acronym

CRI

Study objectives

The consumption of a dietary supplement containing *Lactobacillus crispatus* strains is safe and helps to improve vaginal and gastrointestinal microbiota

Ethics approval required

Old ethics approval format

Ethics approval(s)

Study design

Randomised, double blind, placebo controlled crossover trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Healthy female

Interventions

1. Healthy volunteers will be randomly allocated according to a random number table to one of four groups and will take one capsule per day for 1 week followed by 2 weeks of washout, another 1 week capsules consumption followed by 2 weeks of washout:

1.1. A capsule containing five different *Lactobacillus crispatus* strains: each of strain in dose 1×10^9 colony forming units (370 mg)

1.2. Control: placebo product in capsulated form containing sucrose

2. Bodyweight will be measured

3. Participants will be asked to assess their wellbeing and gastrointestinal effects, and provide blood, self-collected vaginal swabs and faecal samples at every visit.

Intervention Type

Supplement

Primary outcome measure

1. To evaluate the safety and tolerability of consumption of probiotic capsules (5 different *L. crispatus* strains per capsule)

1.1. blood analysis (C-reactive protein, liver and renal function indices)

1.2. The self-reported questionnaire is applied containing questions on well-being, and habitual gastrointestinal symptoms (abdominal pain, flatulence, bloating, stool frequency) and changes in discharge

Secondary outcome measures

1. Change in total *Lactobacillus* counts in faecal and vaginal samples

2. Gastrointestinal and vaginal colonization of ingested *L. crispatus* strains

3. Change in Nugent score level

Overall study start date

01/02/2015

Completion date

31/08/2015

Eligibility

Key inclusion criteria

1. Desire to participate
2. Age 18–50 years
3. Signed informed consent
4. Participants considered themselves 'healthy'
5. Screening blood tests (blood glucose, glycated haemoglobin, inflammatory indices, liver and kidney functional tests)

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

50 persons, 10 subjects in each arm

Key exclusion criteria

1. Diabetes and acute infection
2. Food allergy
3. Use of any antimicrobial drug within past month
4. Current use of any regular concomitant medication, including medical preparations, non-steroidal anti-inflammatory drugs and antioxidant vitamins
5. Pregnancy or breastfeeding
6. History or clinical signs of cardiovascular abnormalities

Date of first enrolment

01/03/2015

Date of final enrolment

31/05/2015

Locations

Countries of recruitment

Estonia

Study participating centre

Competence Centre on Health Technologies

Tiigi 61b

Tartu

Estonia

50410

Sponsor information

Organisation

Tervisetehnoloogiate Arenduskeskus AS (Competence Centre on Health Technologies)

Sponsor details

Tiigi 61b

Tartu

Estonia

50410

Sponsor type

Research organisation

Website

www.ccht.ee

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Tervisetehnoloogiate Arenduskeskus AS (Competence Centre on Health Technologies)

Results and Publications

Publication and dissemination plan

1. Presentation of results at 9th Probiotics, Prebiotics, New Foods in September 2017, Rome (Italy)
2. Publication after December 2016 (e.g., in Applied Biochemistry and Microbiology, Beneficial Microbes, Journal of Applied Microbiology)

Intention to publish date

31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration