

# Safety and efficacy of putative vaginal probiotics in healthy women

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| <b>Submission date</b><br>11/03/2015   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>16/04/2015 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>22/05/2019       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data<br><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  
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# Contact information

## Type(s)

Scientific

## Contact name

Prof Reet Mändar

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

244/T-14

# Study information

## Scientific Title

Safety and efficacy of potential vaginal probiotics administered 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)

Ethics Review Committee on Human Research of the University of Tartu, 19/01/2015, ref: 244/T-14

## Study design

Randomised, double blind, placebo controlled crossover trial

## Primary study design

Interventional

## Study type(s)

Quality of life

## 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  $1 \times 10^9$  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(s)

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

## Key secondary outcome(s)

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

## 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**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)

**ROR**

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

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Tervisetehnoloogiate Arenduskeskus AS (Competence Centre on Health Technologies)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration