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Safety and efficacy of putative vaginal probiotics in healthy women

Submission date
11/03/2015

Recruitment status
No longer recruiting

Registration date
16/04/2015

Overall study status
Completed

Last Edited
22/05/2019

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Study website
N/A

Contact information

Type(s)
Scientific

Contact name
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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)

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

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 1x10^9 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
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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