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Clinical and microbiological efficacy of new probiotics in vaginal discharge disturbances

Submission date
04/10/2016

Recruitment status
No longer recruiting

Registration date
13/02/2017

Overall study status
Completed

Last Edited
02/03/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many women will experience a vaginal infection at some point in their lives (vaginitis). The two most common types of vaginitis are caused by vaginal candidiasis (yeast infection, more commonly known as thrush) and bacterial vaginosis (overgrowth of uncommon bacteria in the vagina). Both of these conditions are thought to be caused by an imbalance in the normal bacteria that live in the vagina. Probiotics are live bacteria that are thought to be beneficial for health, possibly by increasing “good” bacteria (that doesn’t damage health) and reducing “bad” bacteria (that is potentially harmful) in the digestive system (gut). They are safe and cheap and most often used as food supplements. The aim of this study is to find out whether probiotics are a safe and effective treatment for bacterial vagionosis and vaginal candidiasis.

Who can participate?
Women aged between 18 and 50 who suffer from repeated bacterial vagionosis or vaginal candidiasis.

What does the study involve?
Participants are divided into two groups, depending on the condition they are suffering from (bacterial vagionosis or vaginal candidiasis). In each group, participants are randomly allocated to one of three groups who each receive different treatments. Those in the first group receive a probiotic combination nr II oral (by mouth) capsule, those in the second group receive a probiotic combination nr II vaginal capsule and those in the third group receive a placebo (dummy drug) to take by mouth. In all groups, participants are treated daily for 20 day periods over three months. To evaluate patient’s safety all the study participants are asked to fill-up special questionnaire about their well-being and different gastrointestinal and vaginal discharge symptoms during the whole study period, and asked to give blood and vaginal samples, taken by nurse or gynecologist at the clinic and self-collected vaginal swabs.

What are the possible benefits and risks of participating?
Participants benefit from receiving more information about their health than they would usually expect. There is a small risk of bruising, bleeding and discomfort during blood testing.

Where is the study run from?
Medita Clinic (Estonia)

When is the study starting and how long is it expected to run for?
April 2016 to December 2019

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

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Additional identifiers

Clinical Trials Information System (CTIS)
2016-003638-25

Protocol serial number
CRI-BV/CRI-VC

Study information

Scientific Title
Clinical and microbiological efficacy of novel probiotics in vaginitis

Acronym
CRI-BV/CRI-VC

Study objectives
The combination of Lactobacillus crispatus strains are safe and may relieve bacterial vaginosis and vaginal candidiasis symptoms and decreasing bacterial vaginosis and vaginal candidiasis recurrent episodes.

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: 256/T-13

Study design
Randomised double blind placebo controlled parallel trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vaginitis

Interventions
This study consists of two sub-studies in which participants are bacterial vaginosis (CRI-BV) or vaginal candidiasis (CRI-VC) patients.

Sub-study 1 - CRI-BV:
Participants will be randomly allocated according to a random number table to one of three groups.
Group 1: Participants receive a probiotic combination nr I oral capsule with dosages 3xe10 CFU per day
Group 2: Participants receive a probiotic combination nr I vaginal capsule with dosages 3xe10 CFU per day
Group 3: Participants receive a placebo oral capsule per day containing maltodextrin

Sub-study 2 - CRI-VC:
Participants will be randomly allocated according to a random number table to one of three groups.
Group 1: Participants receive a probiotic combination nr II oral capsule with dosages 3xe10 CFU per day
Group 2: Participants receive a probiotic combination nr II vaginal capsule with dosages 3xe10 CFU per day
Group 3: Participants receive a placebo oral capsule per day, containing maltodextrin

In both sub-studies, participants take all capsules together over 3 months, for 3 lots of 20 days. The follow-ups (study visits) take place after every 20 days capsule consumption. The wash-out period between the each treatment cycle is 7 days (during the menstruation time). At baseline, participants are asked to give vaginal swabs and blood samples. After the first two 20 day treatment cycle, participants attend study visits and are asked to bring self-collected vaginal swabs. After the final 20 day treatment cycle participants again provide vaginal swabs and blood samples.

Intervention Type

Supplement

Primary outcome(s)
1.Safety and tolerability of consumption of probiotic capsules (3 different L. crispatus strains in vaginal capsules and 2 different L. crispatus strains in oral capsules) is assessed through:
1.1. Blood analysis (C-reactive protein, liver and renal function indices) taken by the gyneogologist at baseline and forth visit (90 days)
1.2 Microbiological culture and Amsel criteria testing by the gynecologist (vaginal swabs) at baseline visit
1.3 A questionnaire designed for the purpose of this study containing questions on wellbeing, habitual gastrointestinal symptoms (abdominal pain, flatulence, bloating, stool frequency) and changes in discharge at baseline, first, second and third visit (after 20, 40 and 60 days)

Key secondary outcome(s))
1. Total Lactobacillus counts are measured using cultures from faecal samples and vaginal swabs at baseline, after 20 days, 40 days, 60 days and 90 days
2. Gastrointestinal and vaginal colonization of ingested L. crispatus strains at baseline, after 20 days, 40 days, 60 days and 90 days
3. Total bacterial account (Lactobacillus, Gardnerella vaginalis, Mobiluncus) is measured by assessing Nugent score level at at baseline, after 20 days, 40 days, 60 days and 90 days

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Sub-study 1 - CRI-BV
1. Female
2. Aged between 18 and 50 years
3. Recurrent bacterial vagionosis episodes (diagnosed with complaints and through Amsel criteria, confirmation with microscopy in 2 days)

Sub-study 2 - CRI-VC
1. Female
2. Aged between 18 and 50 years
3. Recurrent vaginal candidiasis episodes (diagnosed with complaints and clinical signs confirmation with culture testing in 2 days)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
182

Key exclusion criteria
Sub-study 1 - CRI-BV
1. Pregnancy
2. Breastfeeding
3. Aged under 18 years or over 50 years
4. Sexually transmitted infections
5. Diagnosis of vaginal candidiasis

Sub-study 2 - CRI-VC
1. Pregnancy
2. Breat feeding
3. Aged under 18 years or over 50 years
4. Sexually transmitted infections
5. Diagnosis of bacterial vaginosis

Date of first enrolment
01/11/2016

Date of final enrolment
01/12/2018

Locations

Countries of recruitment
Estonia

Study participating centre
Medita Clinic
Teguri 37b
Tartu
Estonia
50107

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
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2023	02/03/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes