Effect of probiotic yoghurt on blood indices and intestinal microflora of healthy volunteers

Submission date	Recruitment status	[X] Prospectively registered
25/02/2009	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
06/03/2009	Completed	Results
Last Edited	Condition category	[] Individual participant data
06/03/2009	Other	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

178/T-13

Study information

Scientific Title

Effect of probiotic yoghurt on blood indices and intestinal microflora of healthy volunteers: a randomised double-blind cross-over trial

Acronym

YOG

Study objectives

The consumption of probiotic Lactobacillus plantarum containing yoghurt impacts positively on intestinal microflora, blood pressure and immunological parameters of healthy volunteers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Review Committee on Human Research of the University of Tartu, approved on 19/01/2009 (ref: 178/T-13)

Study design

Randomised double-blind cross-over trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Intestinal microflora, blood pressure and immunological parameters of healthy adults

Interventions

Probiotic yoghurt consumption versus regular yoghurt consumption. Volunteers are randomly allocated to receive either:

- 1. 150 g probiotic yoghurt (group 1) or control yoghurt (group 2) once a day for 3 weeks. Probiotic yoghurt containing Lactobacillus plantarum strain 3 x 10^9 colony forming units [CFU] per q of yoghurt.
- 2. After a two-week washout period, volunteers will be crossed over to another three weeks.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Lactobacillus plantarum

Primary outcome measure

The following will be measured at recruitment, after 3-week intervention, after 2-week washout and at the end of another 3-week intervention:

- 1. Clinical blood indices
- 2. Intestinal microflora

Secondary outcome measures

The following will be measured at recruitment, after 3-week intervention, after 2-week washout and at the end of the trial i.e. at the end of another 3-week intervention:

- 1. The self-reported questionnaire containing questions on welfare, nutritional habits, and habitual gastrointestinal symptoms (abdominal pain, flatulence, bloating, and stool frequency)
- 2. Haematological indices, plasma glucose, total cholesterol (TC), high density lipoprotein (HDL) and low density lipoprotein (LDL) cholesterol, triglyceride and high sensitivity C-reactive protein (hsCRP), Interleukin-6 (IL-6), immunoglobulin levels
- 3. The content of biogenic amines and polyamines in urine
- 4. Reverse transcription polymerase chain reaction (RT-PCR) from fecal samples for monitoring the changes in the counts of lactoflora, L. planatrum and survival of the administered strains
- 5. Denaturing gradient gel electrophoresis (DGGE) used to monitor changes in total fecal microflora after yoghurt consumption

Overall study start date

09/03/2009

Completion date

20/05/2009

Eligibility

Key inclusion criteria

- 1. Wish to participate in the study
- 2. Both males and females, aged 18-65 years
- 3. Healthy (i.e. no known health problems and no medical conditions that require drug therapy)
- 4. Signed informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

Upper age limit

65 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

- 1. History of any gastrointestinal disease
- 2. Use of any antimicrobial agent within the preceding month
- 3. Use of any regular concomitant medication including non-steroidal anti-inflammatory drugs and antioxidant vitamins
- 4. Pregnancy or breastfeeding
- 5. Food allergy
- 6. Diabetes and acute infections

Date of first enrolment

09/03/2009

Date of final enrolment

20/05/2009

Locations

Countries of recruitment

Estonia

Study participating centre

Tartu Ulikool

Tartu

Estonia

50411

Sponsor information

Organisation

Bio-Competence Centre of Healthy Dairy Products Ltd. (Estonia)

Sponsor details

Kreutzwaldi str. 1

Tartu

Estonia 51014 +372 731 3403 ene.tammsaar@emu.ee

Sponsor type

Industry

Website

http://www.tptak.ee

ROR

https://ror.org/02e801388

Funder(s)

Funder type

Government

Funder Name

EU Structural Funds (Estonia) - http://www.struktuurifondid.ee/

Funder Name

Enterprise Estonia (Estonia) - http://www.eas.ee

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration