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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 g 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

18 Years

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
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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