

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

Submission date 25/02/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/03/2009	Condition category Other	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Marika Mikelsaar

Contact details
Tartu Ulikool
Ravila 19
Tartu
Estonia
50411
+372 (0)7 374 179
marika.mikelsaar@ut.ee

Additional identifiers

Protocol serial number
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

Study type(s)

Other

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 3×10^9 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(s)

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

Key secondary outcome(s)

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. plantarum* and survival of the administered strains
5. Denaturing gradient gel electrophoresis (DGGE) used to monitor changes in total fecal microflora after yoghurt consumption

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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)

ROR

<https://ror.org/02e801388>

Funder(s)

Funder type

Government

Funder Name

EU Structural Funds (Estonia) - <http://www.strukturifondid.ee/>

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration