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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registeredProtocol		
10/03/2010				
Registration date 18/03/2010	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
16/12/2022	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Marika Mikelsaar

Contact details

Ravila str 19 Tartu Estonia 50411

marika.mikelsaar@ut.ee

Additional identifiers

Protocol serial number 190T-11

Study information

Scientific Title

Effect of probiotic yoghurt comprising L. plantarum strains TENSIA or INDUCIA on blood indices and intestinal microflora of healthy volunteers: A randomised controlled crossover trial

Acronym

Study objectives

The consumption of yoghurt containing probiotic L. plantarum strains has positive impact on intestinal microbiota and blood indices of healthy volunteers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Review Committee on Human Research of the University of Tartu, 22/02/2010, ref: 190T-11

Study design

Randomised double-blind dietary cross-over intervention study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Blood indices and intestinal microflora

Interventions

The consumption once a day 150g of probiotic yoghurt vs regular yoghurt for 3 weeks. Probiotic yoghurt containing either Lactobacillus plantarum strain TENSIA or INDUCIA (10^9 colony forming units [CFU]/g) After two-week washout period, volunteers are crossed over to another three weeks of probiotic yoghurt or control yoghurt administration.

Intervention Type

Biological/Vaccine

Primary outcome(s)

- 1. The health indices of study participants (body mass index, blood pressure) are assessed at the recruitment and after 3 weeks of probiotic treatment.
- 2. The self-reported questionnaire is applied containing questions on welfare, and habitual gastrointestinal symptoms (abdominal pain, flatulence, bloating, and stool frequency), measured once a week during the trial

Fasting blood, faecal samples and morning urine will be taken at the recruitment, after 3 weeks of probiotic treatment, after washout and after placebo treatment.

- 3. Haematological indices will be measured by standard laboratory methods using certified assays in the local clinical laboratory (United Laboratories of Tartu University Clinics, Estonia)
- 3.1. Haemoglobin
- 3.2. White blood cell count
- 3.3. Red blood cell count
- 3.4. Platelet count
- 3.5. Plasma glucose
- 3.6. Albumin

- 3.7. Total cholesterol (TC)
- 3.8. Low-density lipoprotein cholesterol (LDL)
- 3.9. High-density lipoprotein cholesterol (HDL)
- 3.10. Triglyceride
- 3.11. High-sensitive C-reactive protein (hs-CRP)
- 3.12. Interleukin 6 (IL-6)
- 4. Increased counts of total faecal lactobacilli, measured by Reverse Transcriptase Polymerase Chain Reaction (RT-PCR)

Key secondary outcome(s))

Immunological parameters from blood will be measured by routine biochemical analyses in local clinical lab and also by Evidence investigator

- 1. Significantly increased circulation of polyamines in host, measured by urine gas chromotography
- 2. Immune stimulation (both cellular and humoral immunity)

Completion date

24/05/2010

Eligibility

Key inclusion criteria

- 1. Wish to participate in the study
- 2. Aged 18 years and over, both sexes
- 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

Sex

All

Key exclusion criteria

- 1. History of any gastrointestinal disease
- 2. Use of any antimicrobial drug within last month
- 3. Use of any regular concomitant medication, including medical preparations
- 4. Food allergy
- 5 Pregnancy or breastfeeding

Date of first enrolment

Date of final enrolment 24/05/2010

Locations

Countries of recruitment

Estonia

Study participating centre Ravila str 19 Tartu

Estonia 50411

Sponsor information

Organisation

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

ROR

https://ror.org/02e801388

Funder(s)

Funder type

Industry

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015		Yes	No
Results article		01/05/2022	16/12/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes