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

Submission date	Recruitment status	[X] Prospectively registered
10/03/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/03/2010	Completed	[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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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
JOG 2

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

Secondary study design
Randomised cross over trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please contact Dr Pirje Hütt [pirje.hutt@ut.ee] to request a patient information sheet (in Estonian)

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 measure

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)

Secondary outcome measures
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)

Overall study start date
29/03/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120 volunteers recruited from GP clinics (60 per intervention group, subdivided to 30 test subjects & 30 controls)

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
29/03/2010

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)

Sponsor details
Kreutzwaldi str 1
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Estonia
51014

+372 (0)731 3411
ene.tammsaar@tptak.ee

Sponsor type
Industry

Website
http://www.tptak.ee

ROR
https://ror.org/02e801388

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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