

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

Submission date 10/03/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/03/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/12/2022	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

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 chromatography
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

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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