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Effect of probiotic yoghurt (L. plantarum strain TENSIA) on healthy volunteers

Submission date 24/01/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/06/2011	**Overall study status** Completed	
Last Edited 07/02/2022	**Condition category** Digestive System	

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
200-T4 from 17/01/2010

Study information

Scientific Title
Effect of probiotic yoghurt comprising L. plantarum strain TENSIA on blood indices and intestinal microflora of healthy volunteers: A randomised controlled crossover trial

Acronym
JOG3

Study objectives
The consumption of yoghurt containing probiotic L. plantarum strain TENSIA has positive impact on blood indices 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 the 17th January 2010 (ref: 200-T4)

Study design
Randomised double-blind cross-over intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Blood indices, intestinal microflora

Interventions
The consumption once a day 150 g of probiotic yoghurt versus regular yoghurt for 3 weeks. Probiotic yoghurt containing either Lactobacillus plantarum strain TENSIA (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. Fasting blood samples are collected.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The health indices of study participants (height, weight, body mass index, blood pressure) assessed at the recruitment, after 3 weeks of probiotic treatment, after washout and after 3-week placebo treatment
2. The self-reported questionnaire containing questions on welfare, and habitual gastrointestinal symptoms (abdominal pain, flatulence, bloating, and stool frequency), measured once a week during the trial
3. Haematological indices (haemoglobin, white blood cell count, red blood cells, platelets), plasma glucose, albumin, total cholesterol, low density lipoprotein (LDL)-cholesterol, high density lipoprotein (HDL)-cholesterol, triglycerides, high sensitivity C reactive protein (hs-CRP) and interlukin (IL)-6 measured at the recruitment, after 3 weeks of probiotic treatment, after washout and after 3-week placebo treatment

Secondary outcome measures
Circulation of polyamines in host, oxidised low density lipoprotein (oxLDL), 8-isoprostanes, adiponectine, leptin, cytokines and growth factors (IL1 alfa, IL1beta, IL2, IL4, IL6, IL8, IL10, VEGF, EDG, ITFgamma, TNFalfa, MCP-1), osteoprotegerin

Overall study start date
07/02/2011

Completion date
04/04/2011

Eligibility

Key inclusion criteria
1. Wish to participate in the study
2. Aged 18 years and over, either sex
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
100 persons of both sexes, divided into in two groups

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
07/02/2011

Date of final enrolment
04/04/2011

Locations

Countries of recruitment
Estonia

Study participating centre
Ravila 19
Tartu
Estonia
50411

Sponsor information

Organisation
BioCC OÜ

Sponsor details
Kreutzwaldi 1
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Sponsor type
Hospital/treatment centre

Website
http://www.tptak.ee

Funder(s)

Funder type
Industry

Funder Name
Bio-Competence Centre of Healthy Dairy Products LLC (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