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Effect of probiotic cheese on blood indices and intestinal microflora of healthy volunteers and elderly individuals

Submission date 18/09/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/10/2009	**Overall study status** Completed	
Last Edited 08/03/2016	**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
184/T-10

Study information

Scientific Title
Effect of probiotic cheese on blood indices and intestinal microflora of healthy adult and healthy elderly volunteers: a randomised, double-blind, dietary cross-over intervention study

Acronym
TE4

Study objectives
1. The consumption of a probiotic Lactobacillus plantarum strain containing cheese affects positively the functions of the cardio-vascular system of human body. There is a negative correlation between the counts of fecal lactobacilli counts and blood pressure.
2. The consumption of a probiotic Lactobacillus plantarum strain containing cheese has positive impact on intestinal microbiota and 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, 26/08/2009, ref: 184/T-10

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 use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Blood indices and intestinal microflora

Interventions
Probiotic cheese consumption versus regular cheese consumption.

Group I:
Volunteers are randomly allocated to receive either:

1. 50 g probiotic cheese or control cheese once a day for 3 weeks. Probiotic cheese containing Lactobacillus plantarum strain 10^9 colony forming units [CFU] per g of cheese
2. After two-week washout period, volunteers are crossed over to another three weeks of probiotic cheese or control cheese administration.

Group II:
Volunteers receive once 50 g of cheese containing L. plantarum strain 10^9 CFU/g and 4 days later 50 g of control cheese.

Intervention Type
Biological/Vaccine

Primary outcome measure
Group I:
Blood, urine and faecal samples are collected at the recruitment, after 3 weeks of probiotic treatment, after a 2-week wash-out period and after a 3-week placebo treatment. The survival of the probiotic strain in gastrointestinal tract (GIT) and its effect on intestinal microflora and clinical blood indices of healthy volunteers is measured.

Group II:
At the recruitment and 6 hours after cheese consumption the arterial elasticity will be assessed. After 6 hours another blood sample is collected and after 4 days the whole procedure is repeated.

Secondary outcome measures
Group I:
1. The assessment of the health indices of study participants (body mass index, blood pressure), measured at the recruitment, after 3 weeks of probiotic treatment, after a 2-week wash-out period and after a 3-week placebo treatment
2. The self-reported questionnaire is applied containing questions on welfare, nutritional habits, and habitual gastrointestinal symptoms (abdominal pain, flatulence, bloating, and stool frequency), measured once a week during the trial
3. To determine haematological indices (haemoglobin, white blood cell count, red blood cells, platelets), plasma glucose, albumin, total cholesterol (TC), low-density lipoprotein cholesterol (LDL), high-density lipoprotein cholesterol (HDL), triglyceride and high-sensitive C-reactive protein (hs-CRP), interleukin 6 (IL-6), will be measured at the recruitment, after 3 weeks of probiotic treatment, after a 2-week wash-out and after a 3-week placebo treatment
5. Biogenic amines from urine samples will be measured at the recruitment, after 3 weeks of probiotic treatment, after a 2-week wash-out period and after a 3-week placebo treatment
6. Faecal samples will be analysed for the changes in the counts of lactic acid bacteria

Group II:
1. The assessment of the health indices of study participants (body mass index, blood pressure), measured at recruitment
2. Faecal samples are collected at recruitment and will be analysed for the changes in the counts of lactic acid bacteria
3. Haematological indices will be measured at recruitment and 6 hours later (haemoglobin, white blood cell count, red blood cells, platelets), plasma glucose, albumin, total cholesterol (TC), low-density lipoprotein cholesterol (LDL), high-density lipoprotein cholesterol (HDL), triglyceride and high-sensitive C-reactive protein (hs-CRP), interleukin 6 (IL-6), IgM, IgA, IgG, oxidative stress markers: oxLDL, several cytockines and growth factors (IL1alfa, IL1beta, IL2, IL4, IL6, IL8, IL10,

VEGF, EDG, ITF-gamma, TNFalfa, MCP-1)
4. 8-isoprostanes and creatinine is measured from the urine samples collected at recruitment

Overall study start date
05/10/2009

Completion date
28/11/2009

Eligibility

Key inclusion criteria
1. Wish to participate in the study
2. Aged 18 years and over (group I), aged over 60 (Group II), 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
Other

Lower age limit
18 Years

Sex
Both

Target number of participants
Two groups of volunteers: Group I: 200 persons and Group II: 10 persons

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 (Group I)

Date of first enrolment
05/10/2009

Date of final enrolment
28/11/2009

Locations

Countries of recruitment
Estonia

Study participating centre
Ravila 19
Tartu
Estonia
50411

Sponsor information

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

Sponsor details
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Sponsor type
Industry

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Funder(s)

Funder type
Industry

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

Funder Name
University of Tartu (Estonia) - Department of Microbiology, Faculty of Medicine

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	01/05/2015		Yes	No