

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/10/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/03/2016	Condition category Digestive System	<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

Protocol serial number
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

Study type(s)

Quality of life

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(s)

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.

Key secondary outcome(s)

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 cytokines 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

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

Healthy volunteers allowed

No

Age group

Other

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 (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

ROR

<https://ror.org/02e801388>

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

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