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

Submission date	Recruitment status
18/03/2009	No longer recruiting
Registration date	**Overall study status**
30/04/2009	Completed
Last Edited	**Condition category**
02/05/2013	Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
177 /T-13

Study information

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

Study objectives
The consumption of probiotic Lactobacillus plantarum-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 approved on the 12th December 2008 (ref: 177/T-13)

Study design
Randomised double-blind dietary cross-over intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Intestinal microflora

Interventions
Probiotic cheese consumption versus control cheese consumption. Volunteers were randomly allocated to receive either:
1. 50 g probiotic cheese (containing Lactobacillus plantarum strain 3 x 10^9 Colony Forming Units [CFU] per gram of cheese) (group 1, n = 12) once a day for three weeks
2. 50 g control cheese (group 2, n = 12) once a day for three weeks

After a two-week wash-out period, volunteers were crossed over to another three weeks of probiotic cheese or control cheese administration.

Intervention Type

Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Lactobacillus plantarum

Primary outcome measure
To assess the safety of cheese comprising the probiotic Lactobacillus plantarum strain in healthy elderly subjects. The survival of the probiotic strain in gastrointestinal tract (GIT) and its effect on intestinal microflora and clinical blood indices of healthy volunteers will be measured at the recruitment, after a 3-week of probiotic treatment, after a 2-week wash-out and after a 3-week placebo treatment.

Secondary outcome measures
1. 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
2. The assessment of the health indices of healthy elderly (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
3. 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
4. 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), immunoglobulins (IgA, IgM, IgG) levels 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 urines 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 clostridia (including C. difficile), total anaerobes, enterococci, E. coli and lactic acid bacteria

Overall study start date
03/01/2009

Completion date
30/04/2009

Eligibility

Key inclusion criteria
1. Wish to participate in the study
2. Aged over 65 years, 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
Senior

Sex
Both

Target number of participants
24 elderly volunteers (both sexes)

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

Date of first enrolment
03/01/2009

Date of final enrolment
30/04/2009

Locations

Countries of recruitment
Estonia

Study participating centre
Ravila str 19
Tartu
Estonia
50411

Sponsor information

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

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
Government

Funder Name
Estonian Science Foundation (Estonia) - http://www.etf.ee/

Funder Name
EU Structural Funds (Estonia) - http://www.struktuurifondid.ee/

Funder Name
Enterprise Estonia (Estonia) - http://www.eas.ee

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	01/10/2012		Yes	No