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

Submission date 31/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/07/2007	**Overall study status** Completed	
Last Edited 02/05/2013	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Marika Mikelsaar

Contact details
Ravila str 19
Tartu
Estonia
50411
+372 (0)7 374 179
marika.mikelsaar@ut.ee

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
158/10

Study information

Scientific Title

Acronym
TAK

Study objectives
The consumption of probiotic Lactobacillus plantarum-containing cheese has positive impact on intestinal microflora of healthy volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Ethics Review Committee on Human Research of the University of Tartu on 26th March 2007 (ref: 158/10).

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Intestinal microflora of healthy volunteers

Interventions
Probiotic cheese consumption versus regular cheese consumption. Volunteers were randomly allocated to receive either:
1. 50 g probiotic cheese (group 1, n = 12) or control cheese (group 2, n = 12) once a day for three weeks. Probiotic cheese containing Lactobacillus plantarum strain 3 x 10^9 Colony Forming Units [CFU] per gram of cheese
2. After a two-week washout period, volunteers were crossed over to another three weeks of probiotic cheese or control cheese administration

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Probiotic Lactobacillus plantarum-containing cheese

Primary outcome measure
To assess the safety of the novel probiotic Lactobacillus plantarum with antimicrobial properties and the strain containing cheese on healthy subjects. The survival of the probiotic strain in Gastrointestinal Tract (GIT) and its effect on faecal lactoflora, measured on 25/04/07, 16/05/07, 30/05/07 and 20/06/07.

Secondary outcome measures
1. To assess the health indices of healthy adults (body mass index, blood pressure), measured on 25/04/07, 16/05/07, 30/05/07 and 20/06/07
2. The self-reported questionnaire was 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, ferritin, Total Cholesterol (TC), Low-Density Lipoprotein cholesterol (LDL), High-Density Lipoprotein cholesterol (HDL), triglyceride and high-sensitive C-Reactive Protein (hsCRP), Interleukin 6 (IL-6), Immunoglobulins (IgA, IgM, IgG) levels, measured on 25/04/07, 16/05/07, 30/05/07 and 20/06/07
4. To determine in urine the content of biogenic amines
5. Faecal samples were analysed for the changes in the counts of clostridia (including C. difficile), total anaerobes, enterococci, E. coli and lactic acid bacteria, collected also at 25/04/07, 16/05/07, 30/05/07 and 20/06/07 and stored at -20°C. Faecal samples are analysed step-by-step during one year
6. Denaturated Gradient Gel Electrophoresis (DGGE) was used to monitor changes in total faecal microflora after cheese consumption, analysis from faecal samples is performed in September 2007

Overall study start date
25/04/2007

Completion date
20/06/2007

Eligibility

Key inclusion criteria
1. Wish to participate in the study
2. Aged 20 to 50 years
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

Sex
Both

Target number of participants
25 adult volunteers (9 men and 16 women)

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. Pregnancy or breastfeeding
5. Food allergy

Date of first enrolment
25/04/2007

Date of final enrolment
20/06/2007

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
Tartu
Estonia
51014
+372 (0)731 3403
Ene.Tammsaar@emu.ee

Sponsor type
Industry

Website
http://www.tptak.ee

ROR
https://ror.org/02e801388

Funder(s)

Funder type
Industry

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

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