

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
Registration date 02/07/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/05/2013	Condition category Digestive System	☐ 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
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).

Primary study design

Interventional

Study design

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

Study type(s)

Quality of life

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 3×10^9 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

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. 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

ROR

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

Funder(s)

Funder type

Industry

Funder Name

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

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?
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[Results article](#)

results

01/10/2012

Yes

No