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

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

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

#### Contact name

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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).

### 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

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(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?

Results article results 01/10/2012 Yes

No