

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

<b>Submission date</b> 18/09/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/03/2016	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## 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

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?
<a href="#">Results article</a>	results	01/05/2015		Yes	No