

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

<b>Submission date</b> 18/03/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 30/04/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/05/2013	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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**  
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

**Study type(s)**

Treatment

**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  $3 \times 10^9$  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(s)**

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.

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Senior

**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

**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

**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.strukturifondid.ee/>

**Funder Name**

Enterprise Estonia (Estonia) - <http://www.eas.ee>

# 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	01/10/2012		Yes	No