

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

<b>Submission date</b> 10/03/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/03/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/12/2022	<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**  
190T-11

## Study information

**Scientific Title**  
Effect of probiotic yoghurt comprising *L. plantarum* strains TENSIA or INDUCIA on blood indices and intestinal microflora of healthy volunteers: A randomised controlled crossover trial

**Acronym**

### **Study objectives**

The consumption of yoghurt containing probiotic *L. plantarum* strains has positive impact on intestinal microbiota and blood indices of healthy volunteers.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The Ethics Review Committee on Human Research of the University of Tartu, 22/02/2010, ref: 190T-11

### **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**

The consumption once a day 150g of probiotic yoghurt vs regular yoghurt for 3 weeks. Probiotic yoghurt containing either *Lactobacillus plantarum* strain TENSIA or INDUCIA ( $10^9$  colony forming units [CFU]/g) After two-week washout period, volunteers are crossed over to another three weeks of probiotic yoghurt or control yoghurt administration.

### **Intervention Type**

Biological/Vaccine

### **Primary outcome(s)**

1. The health indices of study participants (body mass index, blood pressure) are assessed at the recruitment and after 3 weeks of probiotic treatment.
2. The self-reported questionnaire is applied containing questions on welfare, and habitual gastrointestinal symptoms (abdominal pain, flatulence, bloating, and stool frequency), measured once a week during the trial

Fasting blood, faecal samples and morning urine will be taken at the recruitment, after 3 weeks of probiotic treatment, after washout and after placebo treatment.

3. Haematological indices will be measured by standard laboratory methods using certified assays in the local clinical laboratory (United Laboratories of Tartu University Clinics, Estonia)

- 3.1. Haemoglobin
- 3.2. White blood cell count
- 3.3. Red blood cell count
- 3.4. Platelet count
- 3.5. Plasma glucose
- 3.6. Albumin

- 3.7. Total cholesterol (TC)
- 3.8. Low-density lipoprotein cholesterol (LDL)
- 3.9. High-density lipoprotein cholesterol (HDL)
- 3.10. Triglyceride
- 3.11. High-sensitive C-reactive protein (hs-CRP)
- 3.12. Interleukin 6 (IL-6)
- 4. Increased counts of total faecal lactobacilli, measured by Reverse Transcriptase - Polymerase Chain Reaction (RT-PCR)

### **Key secondary outcome(s)**

Immunological parameters from blood will be measured by routine biochemical analyses in local clinical lab and also by Evidence investigator

- 1. Significantly increased circulation of polyamines in host, measured by urine gas chromatography
- 2. Immune stimulation (both cellular and humoral immunity)

### **Completion date**

24/05/2010

## **Eligibility**

### **Key inclusion criteria**

- 1. Wish to participate in the study
- 2. Aged 18 years and over, both sexes
- 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

### **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

### **Date of first enrolment**

29/03/2010

**Date of final enrolment**

24/05/2010

## Locations

**Countries of recruitment**

Estonia

**Study participating centre**

Ravila str 19

Tartu

Estonia

50411

## Sponsor information

**Organisation**

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

**ROR**

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

## Funder(s)

**Funder type**

Industry

**Funder Name**

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

## Results and Publications

**Individual participant data (IPD) sharing plan**

Not provided at time of registration

**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	01/02/2015		Yes	No
<a href="#">Results article</a>		01/05/2022	16/12/2022	Yes	No