

# Effect of different doses of *L. planatum* TENSIA containing probiotic cheese on clinical parameters of 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> 18/03/2010	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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-10 from 22.02.2010

## Study information

**Scientific Title**  
Effect of different doses of *L. planatum* TENSIA containing probiotic cheese on blood indices and intestinal microflora of healthy adult volunteers: An open label, interventional study

## Acronym

TE 5

## Study objectives

1. The consumption of a probiotic *Lactobacillus plantarum* strain containing cheese in daily (high) dose of 100g (probiotic dose being  $10^{11}$  CFU)
  - 1.1. is safe: no negative gastrointestinal effect, no elevated total cholesterol and no negative shifts in cholesterol fractions
  - 1.2. affects positively the functions of the cardio-vascular system of human body.
2. The consumption of a probiotic *Lactobacillus plantarum* strain containing cheese in daily (low) dose of 100g (probiotic dose being  $10^5$  Colony Forming Units [CFU]) has positive impact on 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 approved on the 22nd of February 2010 (ref: 190T-10)

## Study design

Open interventional dose safety study

## Primary study design

Interventional

## Study type(s)

Other

## Health condition(s) or problem(s) studied

blood indices and intestinal microflora

## Interventions

Probiotic cheese consumption

Group I of volunteers 100 g probiotic cheese once a day for 3 weeks in a daily dose of probiotic being  $10^5$  CFU

Group II of volunteers 100 g probiotic cheese once a day for 3 weeks in a daily dose of probiotic being  $10^{11}$  CFU

Blood, urine and faecal samples are collected at the recruitment, and after 3 weeks of probiotic treatment

Samples of fasting blood, fecal and urine samples will be collected at recruitment and at the end of the trial after administration of the *L. plantarum* TENSIA comprising cheese.

## Intervention Type

Other

## Phase

Not Specified

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

1. The health indices of study participants are assessed at the recruitment and after 3 weeks of probiotic treatment.
  - 1.1. Height
  - 1.2. Weight
  - 1.3. Body mass index (BMI)
  - 1.4. Blood pressure
2. The self-reported questionnaire is applied containing questions on welfare, and habitual gastrointestinal symptoms (abdominal pain, flatulence, bloating, and stool frequency), is filled once a week during the trial
3. Haematological indices will be determined at the recruitment and after 3 weeks of probiotic treatment. 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 cells count
  - 3.4. Platelet count
4. Routine biochemical indices will be determined at the recruitment and after 3 weeks of probiotic treatment
  - 4.1. Albumin
  - 4.2. Ferritine
  - 4.3. Plasma glucose
  - 4.4. High-sensitive CRP (hs-CRP)
  - 4.5. Total cholesterol
  - 4.6. LDL-cholesterol (LDL)
  - 4.7. HDL-cholesterol (HDL)
  - 4.8. Triglycerides
  - 4.9. Serum creatinine
  - 4.10. Alanine transaminase (ALAT)
  - 4.11. Aspartate transaminase (ASAT)
  - 4.12. Immunoglobulin IgE levels
5. Safety of high doses of TENSIA

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

Positive impact on human health

### **Completion date**

14/06/2010

## **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**

10/05/2010

**Date of final enrolment**

14/06/2010

**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**

### **IPD sharing plan summary**

Not provided at time of registration