# Effect of probiotic yoghurt (L. plantarum strain INDUCIA) on healthy volunteers

Submission date	Recruitment status	Prospectively registered
24/01/2011	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
04/03/2011	Completed	Results
Last Edited	Condition category	Individual participant data
07/02/2022	Digestive System	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

## Type(s)

Scientific

#### Contact name

Prof Marika MIkelsaar

#### Contact details

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# Additional identifiers

## Protocol serial number 199/T6 from 20.12.2010

# Study information

#### Scientific Title

Effect of probiotic yoghurt comprising L. plantarum strain 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 strain has positive impact on 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 20th December 2010 (ref: 199/T6)

#### 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

Blood indices, intestinal microflora

#### **Interventions**

The consumption once a day 150 g of probiotic yoghurt versus regular yoghurt for 3 weeks. Probiotic yoghurt containing either Lactobacillus plantarum strain 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. Fasting blood samples are collected.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

- 1. The health indices of study participants (eight, weight, body mass index, blood pressure) assessed at the recruitment, after 3 weeks of probiotic treatment, after washout and after 3-week placebo treatment
- 2. The self-reported questionnaire containing questions on welfare, and habitual gastrointestinal symptoms (abdominal pain, flatulence, bloating, and stool frequency), measured once a week during the trial
- 3. Haematological indices (haemoglobin, white blood cell count, red blood cells, platelets), plasma glucose, albumin, total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, hs-CRP and IL-6 measured at the recruitment, after 3 weeks of probiotic treatment, after washout and after 3-week placebo treatment

#### Key secondary outcome(s))

#### Circulation of polyamines in host

#### Completion date

04/04/2011

# **Eligibility**

#### Key inclusion criteria

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

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

07/02/2011

#### Date of final enrolment

04/04/2011

# Locations

#### Countries of recruitment

Estonia

## Study participating centre

#### Ravila 19

Tartu Estonia 50411

# Sponsor information

# Organisation

BioCC OÜ

# Funder(s)

#### Funder type

Industry

#### **Funder Name**

Bio-Competence Centre of Healthy Dairy Products LLC (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?

Participant information sheet Participant information sheet 11/11/2025 No Yes