

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

<b>Submission date</b> 20/03/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/03/2012	<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

### Background and study aims

Hypercholesterolemia (the presence of high levels of cholesterol in the blood) is one of the risk factors for cardiovascular diseases (CVD). The cholesterol threat to health has grown out of dietary changes in developed countries, with increasing consumption of saturated fats, to which the human body has been unable to fully adapt. There is strong evidence that a reduction of LDL-cholesterol by dietary changes would generally reduce the risk of development of CVD, particularly coronary heart disease. The consumption of fermented milk products containing health beneficial probiotic lactic acid bacteria may turn out to be a successful solution to prevent CVD by eliminating various risk factors, including elevated cholesterol levels. The purpose of the study is to assess the efficacy of probiotic yoghurt on lowering blood cholesterol, especially LDL-cholesterol.

### Who can participate?

Generally healthy adult persons aged 18 to 65 with elevated LDL-cholesterol levels, who do not take medication. Patients will be recruited through CP clinics in Southern and Central Estonia.

### What does the study involve?

Participants are randomly allocated into two groups: one group will consume probiotic yoghurt daily for 8 weeks while the other group will consume a non-probiotic yoghurt daily for 8 weeks. Participants are asked to assess their well-being and gastrointestinal (digestive) effects, but also to provide blood, urine and fecal samples to test the effect of the probiotic.

### What are the possible benefits and risks of participating?

The study causes minimal inconvenience to participants. As blood samples are taken by an experienced nurse, the procedure is safe. However, there may be bruising and discomfort at the site of the blood test as with any blood test. The amounts of blood we are taking are small enough that they should not make you feel fatigue or cause anemia. There may be local red reactions at the site of the injections. Study participants will receive an assessment of their health status and if necessary, a free consultation with a nutritionist and/or a specialist.

### Where is the study run from?

The study is carried out in cooperation between BioCC OÜ, the Faculty of Medicine, University of

Tartu, and the Maag Dairy Industry Ltd (Estonia). The study takes place at BioCC OÜ in Tartu, Estonia.

When is the study starting and how long is it expected to run for?  
The study ran from March to April 2012.

Who is funding the study?  
BioCC OÜ (Estonia).

Who is the main contact?  
Dr Pirje Hütt, MD (researcher)  
pirje.hutt@ut.ee

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Marika Mikelsaar

**Contact details**  
University of Tartu  
Faculty of Medicine  
Department of Microbiology  
Ravila 19  
Tartu  
Estonia  
50411  
-  
marika.mikelsaar@ut.ee

## Additional identifiers

**Protocol serial number**  
207/M-11

## Study information

**Scientific Title**  
Effect of probiotic yoghurt comprising L. plantarum strain Inducia on healthy volunteers randomized blinded controlled parallel-designed two-armed study

**Acronym**  
JOG 4

**Study objectives**  
The consumption of probiotic yoghurt with L. plantarum Inducia helps to maintain/lower blood cholesterol especially Low-Density Lipoprotein (LDL) cholesterol

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics Review Committee on Human Research of the University of Tartu, 19/09/2011, ref: 207/M-11

## **Study design**

Randomized blind controlled parallel-designed two-armed intervention phase II trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Elevated LDL cholesterol levels

## **Interventions**

The consumption of a probiotic yoghurt comprising *Lactobacillus plantarum* strain INDUCIA: daily dose of yoghurt 150 g, daily dose of probiotic:  $8 \times 10^9$  colony forming units [CFU]) for 8 weeks vs consumption of control yoghurt (150 g)

## **Intervention Type**

Other

## **Phase**

Phase II

## **Primary outcome(s)**

1. A significant reduction in blood LDL-cholesterol between probiotic and placebo group after 4 and 8 weeks of product intake
2. The first primary end point: reduction in blood LDL-cholesterol in probiotic group after 4 weeks of product intake
3. The second primary end point: reduction in blood LDL-cholesterol in probiotic group after 8 weeks of product intake

Measured at baseline, at 4th week from the beginning of the trial, and at 8th week from the beginning of the trial

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

1. In probiotic group maintenance or significant ( $p < 0.05$ ) reduction of:
  - 1.1. Cholesterol/HDL-cholesterol ratio
  - 1.2. LDL/HDL-cholesterol ratio, triglycerides
  - 1.3. HDL-cholesterol
  - 1.4. Adiponectin levels 8-isoprostanes
  - 1.5. oxLDL-cholesterol
  - 1.6. Leptin
  - 1.7. IL-6
  - 1.8. TNF $\alpha$

- 1.9. HbA1c
- 1.10. OSI
2. Maintenance or significant ( $p < 0.05$ ) increase of:
  - 2.1. HDL-cholesterol
  - 2.2. Ca
  - 2.3. iCa
  - 2.4. Vitamin D

Measured at baseline, at 4th week from the beginning of the trial, and at 8th week from the beginning of the trial

**Completion date**

25/04/2012

## Eligibility

**Key inclusion criteria**

1. A written informed consent
2. Aged between 18 - 65 years
3. No personally known health problems
4. Elevated levels of blood total cholesterol/cholesterol fractions:  $\geq 3.0$  mmol/l for LDL,  $\geq 3.0$  mmol/l for LDL/HDL ratio,  $\geq 5.0$  mmol/l for total cholesterol and  $\geq 1.7$  mmol/l for level of triglycerides
5. No use of any concomitant treatment which could influence the evaluation of the efficacy and the tolerability of the investigational study product, including lipid-lowering drugs (e.g., statins, bile acid sequestrates, cholesterol absorption inhibitors, nicotinic acid), supplementation with e.g. omega-3 fatty acids, calcium, oat fiber, niacin, green tea extract, plant sterols, soy protein, psyllium seed husk or probiotics/prebiotics within the preceding 2 months
6. Willingness to maintain a stable diet and physical activity level
7. Normal or not clinically pronounced safety lab values (clinical chemistry, blood count) except for lipids

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

## **Key exclusion criteria**

1. Pregnancy and breastfeeding
2. A history of gastrointestinal disease, food allergy, diabetes and acute infection within the last 2 weeks prior to enrolment
3. Use of any antimicrobial agents within the preceding 2 months or use of any regular concomitant medication including any non-steroidal anti-inflammatory drugs and antioxidant products 2 weeks
4. Intolerance to the investigational product/its ingredients
5. Any kind of concurrent disease which could influence the evaluation of the efficacy and the tolerability of the investigational study product
6. Any serious organ or systemic diseases
7. High blood pressure (e.g., >140/95 mmHg)
8. Eating disorder
9. Extensive exercise
10. Genetic hyperlipidemia
11. Drug or alcohol abuse
12. Active weight loss > 5 kg in prior 3 months
13. Participation in other studies within the last 30 days/during the study

## **Date of first enrolment**

12/03/2012

## **Date of final enrolment**

25/04/2012

## **Locations**

### **Countries of recruitment**

Estonia

### **Study participating centre**

University of Tartu

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