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

Submission date	Recruitment status	Prospectively registered
20/03/2012	No longer recruiting	[] Protocol
Registration date	Overall study status	[] Statistical analysis plan
26/03/2012	Completed	[X] Results
Last Edited 16/12/2022	Condition category Nutritional, Metabolic, Endocrine	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Secondary study design Randomised controlled trial

Study setting(s) Other

Study type(s) Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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: 8x10^9 colony forming units [CFU]) for 8 weeks vs consumption of control yoghurt (150 g)

Intervention Type

Other

Phase II

Primary outcome measure

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

Secondary outcome measures

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. HLD-cholesterol
- 1.4. Adiponectin levels 8-isoprostanes
- 1.5. oxLDL-cholesterol
- 1.6. Leptin
- 1.7. IL-6
- 1.8. TNFa
- 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

Overall study start date

12/03/2012

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: ≥3.0 mmol/l for LDL, ≥3.0 mmol/l for LDL/HDL ratio, ≥5.0 mmol/l for total cholesterol and ≥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

Age group

Adult

Lower age limit 18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

200

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

Sponsor details Kreutzwaldi 1 Tartu Estonia 51014 ene.tammsaar@tptak.ee

Sponsor type Industry

Website http:// www.tptak.ee

Funder(s)

Funder type Industry

Funder Name Bio-Competence Centre of Healthy Dairy Products LLC (Estonia)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Details

Study outputs

Output type <u>Results article</u> **Date created** 01/05/2022 Date added 16/12/2022

Peer reviewed? Yes Patient-facing? No