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Effect of probiotic yoghurt on the blood cholesterol levels of healthy volunteers

Submission date	Recruitment status	[_] Prospectively registered
17/11/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/12/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/12/2022	Circulatory System	

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) and oxidized LDL (oxLDL) has been shown to play an important role in atherosclerosis (narrowing of the arteries). 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 and oxLDL by dietary changes would generally reduce the risk of CVD, particularly coronary heart disease.
The consumption of fermented milk products containing health beneficial probiotic lactic acid bacteria may help to prevent CVD by eliminating various risk factors, including high cholesterol levels. The aim of this study is to assess the effectiveness of probiotic yoghurt on lowering blood cholesterol, especially oxLDL.

Who can participate?
Generally healthy adults aged 18 to 65 years with elevated LDL-cholesterol levels who do not take medication.

What does the study involve?
Participants are randomly allocated into two groups: one group will consume a 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 taken are small enough that they should not make participants feel fatigue or cause anemia. There may be local red reactions at the site of the injections. 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 was carried out in cooperation between the Bio-Competence Centre of Healthy Dairy Products LLC, the Faculty of Medicine, University of Tartu and the Maag Dairy Industry Ltd (Estonia). The study took place at the Bio-Competence Centre of Healthy Dairy Products LLC in Tartu (Estonia).

When is the study starting and how long is it expected to run for?
February 2014 to April 2015

Who is funding the study?
BioCC OÜ (Estonia)

Who is the main contact?
Merle Rätsep (researcher)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
JOG5/1

Study information

Scientific Title
Effect of yoghurt containing Lactobacillus plantarum Inducia on level of oxLDL-cholesterol and on some oxidative stress related indices of healthy volunteers

Acronym
JOG5

Study objectives
Consumption of yoghurt containing L. plantarum Inducia contributes to the protection of blood lipids (especially low-density lipoprotein [LDL] particles) from oxidative damage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/10/2014, Ethics Review Committee on Human Research of the University of Tartu (Raekoja plats 9, 51004, Tartu, Estonia; +372 (0)737 6215; eetikakomitee@ut.ee), ref: 240/T-11

Study design
Double-blind placebo-controlled (DBPC) parallel-designed two-armed randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Elevated LDL cholesterol levels

Interventions
Participants are randomly allocated to one of two groups. Randomisation is prepared by a study statistician using statistical analysis software and participants are randomly allocated to one of the treatment groups (placebo or verum) applying a 1:1 allocation ratio.

Participants consume a daily dose of a probiotic yoghurt (150 g) containing Lactobacillus plantarum strain INDUCIA (2x10e9 colony-forming units [CFU]) for 8 weeks, or a control yoghurt (150 g).

Intervention Type
Supplement

Primary outcome(s)
Blood oxLDL-cholesterol level measured using blood tests (ELISA) at baseline and weeks 8

Key secondary outcome(s))
1. ox-LDL values measured using blood tests (ELISA) at baseline and weeks 4
2. Total cholesterol, LDL-cholesterol, non-HDL-cholesterol measured by standard laboratory methods in the United Laboratories of Tartu University Hospital (Estonia) from fasting blood serum at baseline, weeks 4 and weeks 8
3. Blood oxidative stress indices measured from blood serum by ELISA at baseline, weeks 4 and weeks 8

Completion date
01/04/2015

Eligibility

Key inclusion criteria

1. A written informed consent
2. Aged between 18 - 65 years
3. No personally known health problems
4. 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) 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)
8. LDL-cholesterol values ≥3.0 mmol/l– 5.3 mmol/l

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
132

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
17/10/2014

Date of final enrolment
04/02/2015

Locations

Countries of recruitment
Estonia

Study participating centre
Bio-Competence Centre of Healthy Dairy Products LLC (Estonia)
Kreutzwaldi 1
Tartu
Estonia
51014

Sponsor information

Organisation
BioCC OÜ

Funder(s)

Funder type
Government

Funder Name
European Regional Development Fund under Project EU30002 of the BioCC OÜ

Alternative Name(s)
Fondo Europeo de Desarrollo Regional, Europäischer Fonds für regionale Entwicklung, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Fundo Europeu de Desenvolvimento Regional, ERDF, FEDER, EFRE, ЕФРР, EFRR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/11/2022	20/12/2022	Yes	No