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

Submission date
20/03/2012

Recruitment status
No longer recruiting

Registration date
26/03/2012

Overall study status
Completed

Last Edited
16/12/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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)
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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
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. TNFα
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
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Sponsor information

Organisation
BioCC OÜ

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Sponsor type
Industry

Website
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2022	16/12/2022	Yes	No