ISRCTN11616457 https://doi.org/10.1186/ISRCTN11616457

The effects of Lactobacillus plantarum INDUCIA® probiotic in healthy volunteers with elevated cholesterol

Submission date
04/10/2022

Recruitment status
No longer recruiting

Registration date
13/01/2023

Overall study status
Completed

Last Edited
08/01/2024

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Mortality from cardiovascular disease is the world leader. In order to reduce the risk of cardiovascular disease, it is recommended to reduce the total serum cholesterol and LDL cholesterol as well as oxidative stress.

There is a focus on functional foods, including foods containing probiotics and food supplements. The positive effects of probiotics on lowering cholesterol and alleviating excessive oxidative stress have been described in scientific articles. Positive results have been obtained with various probiotics in reducing oxidative stress, an important factor for the pathogenesis of cardiovascular disease.

Probiotics are friendly bacteria that are known to improve health in human beings by, amongst other ways, interacting with the bacteria that already live in the gut. The aim of this study is to test if the daily consumption of a probiotic supplement can improve cholesterol metabolism, oxidative stress markers, clinical blood indices and gastrointestinal microbiota of reasonably healthy volunteers with elevated cholesterol.

Who can participate?
Generally healthy people aged between 30 and 65 years old with higher cholesterol levels

What does the study involve?
Participants will be randomly allocated to either a probiotic or a placebo group and asked to take one capsule per day for 12 weeks. Participants will also be asked to assess their well-being and gastrointestinal (digestive) effects, and also to provide blood, urine and fecal samples to test the effect of the probiotic.

What are the possible benefits and risks of participating?
A benefit of participation is that subjects will receive an assessment of their health status and if necessary recommendations for future steps. The study will cause minimal inconvenience to participants. As blood samples are taken by an experienced nurse, the procedure is safe.

However, as with any blood test, there may be bruising and discomfort at the site of the blood test. The amounts of blood will be small enough not to cause fatigue or anemia.

Where is the study run from?
Laboratory for Clinical and Physiological Research, BioCC LLC (Estonia)

When is the study starting and how long is it expected to run for?
From January 2019 to December 2021

Who is funding the study?
BioCC LLC (Estonia)

Who is the main contact?
Ms. Merle Rätsep (Estonia)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IND1

Study information

Scientific Title
Mechanisms of action of a probiotic strain Lactobacillus plantarum INDUCIA® DSM21379 comprising dietary supplement on cholesterol metabolism, oxidative stress markers, clinical

blood indices, and gastrointestinal microbiota of reasonably healthy volunteers with elevated cholesterol

Study objectives
The consumption of a dietary supplement comprising L. plantarum INDUCIA® DSM21379 has a positive effect on any of the following health parameters of reasonably healthy volunteers with elevated cholesterol: cholesterol metabolism, oxidative stress markers, clinical blood indices, and gastrointestinal microbiota.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/11/2018, Research Ethics Committee of the University of Tartu (University of Tartu, Grant Office, Lossi 3, 51003 Tartu, Estonia; +372 737 6215; eetikakomitee@ut.ee), ref: 287 /T-24

Study design
Interventional randomized placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

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

Interventions
Participants were randomly allocated to either the intervention group or the placebo group applying a 1:1 allocation ratio.
Group 1 (verum): Participants take one capsule daily for twelve weeks. The capsule contains a daily dose of a product containing 5x10e9 CFU of L. plantarum INDUCIA®.
Group 2 (placebo): Participants take one capsule daily for twelve weeks. The capsule contains a daily dose of a product containing no active compounds (microcellulose).
Participants take the product daily for twelve weeks and the last study visit will be performed two weeks after the end of the treatment.
All the samples are collected at the run-in, after 8 weeks and at the end of the interventions.

Changes at 8 weeks from baseline and at 12 weeks from baseline are measured for the following outcomes: oxidative stress indices (ELISA), SCFA's content in faeces (HPLC), and changes in lipid fractions.

Intervention Type
Supplement

Primary outcome measure
1. LDL-cholesterol level in blood serum at baseline, and weeks 8, 12 and 14
2. Total-cholesterol level in blood serum at baseline, and weeks 8, 12 and 14
3. Oxidative stress indices measured from blood and urine samples using different ELISA-based assays at baseline, and weeks 8 and 12
4. Gut microflora indices (lactoflora, anaerobes etc) measured from stool samples using molecular approaches and specific primers at baseline, and weeks 8, 12 and 14

Secondary outcome measures
1. Metabolic syndrome indices measured from blood samples using different ELISA-based assays at baseline, and weeks 8 and 12
2. Short-chain fatty acids (SCFA) measured from stool and urine samples using High-Pressure Liquid Chromatography (HPLC) at baseline, and weeks 8, 12 and 14
3. Bile acids concentration measured from stool and urine samples High-Pressure Liquid Chromatography (HPLC) at baseline, and weeks 8, 12 and 14

Overall study start date
01/06/2018

Completion date
30/12/2022

Eligibility

Key inclusion criteria
1. Written informed consent
2. Aged between 30 and 65 years old
3. Willingness to maintain a stable diet and physical activity level
4. Willingness to cease using probiotic products and supplements (except vitamin D) during the study period
5. Normal or not clinically relevant deviations in safety laboratory values
6. One of the following outcomes at the screening visit: LDL-cholesterol value >3.4 mmol/L; LDL-cholesterol/HDL-cholesterol >3.5 mmol/L or total cholesterol/HDL between 3.5 and 4.5 mmol/L

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
70

Total final enrolment
37

Key exclusion criteria
1. Using blood pressure and/or cholesterol lowering drugs/supplements within the last 3 months prior to start of the study (i.e. baseline visit)
2. Diabetes
3. Acute or chronic inflammatory disease
4. Endocrinological disease
5. (Food) allergy
6. Using antibiotic within the last 4 weeks prior to start of the study (i.e. baseline visit)
7. Using NSAIDs regularly
8. Pregnancy and breastfeeding
9. Donor within the last 3 months prior to start of the study (i.e. baseline visit)
10. Smoking
11. Use of any pre-, probiotic or food supplement within the last 2 weeks prior to start of the study
12. Intolerance to the investigational product/its ingredients
13. Acute infection within the last 2 weeks prior to baseline
14. Eating disorder
15. Extensive exercise (daily training of professional athletes)
16. Drug or alcohol abuse

Date of first enrolment
03/01/2019

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
Estonia

Study participating centre
The Laboratory for Clinical and Physiological Research of the BioCC
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Sponsor information

Organisation
BioCC LCC (formerly Bio-Competence Centre of Healthy Dairy Products (Estonia)

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Sponsor type
Industry

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https://ror.org/02e801388

Funder(s)

Funder type
Industry

Funder Name
BioCC LLC Project EU48686 HEALTHY FOOD

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to belonging to a private company.

IPD sharing plan summary
Not expected to be made available