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Effect of kefir containing probiotic Lactobacillus fermentum ME-3 on healthy volunteers

Submission date
21/11/2013

Recruitment status
No longer recruiting

Registration date
05/02/2014

Overall study status
Completed

Last Edited
21/10/2015

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
Both high levels of blood lipids (cholesterol) and oxidative stress have an impact on the risk of cardiovascular diseases. Previous studies have shown that the antioxidative probiotic L. fermentum ME-3 has a positive effect on blood lipid levels. We are carrying out a study to investigate the effects of kefir (a fermented milk drink) with probiotic L. fermentum ME-3 on healthy volunteers with high levels of blood lipids.

Who can participate?
Persons with elevated blood levels of triglycerides, cholesterol and its fractions.

What does the study involve?
Eligible participants will be randomly allocated to either the probiotic group or the placebo group. The probiotic group will receive the probiotic kefir and the placebo group will receive a dummy probiotic kefir for 8 weeks. Body measurements, clinical data, blood, urine and faecal samples will be collected and analysed. The measurements will be carried out at the start of the study and after 4 weeks and 8 weeks.

What are the possible risks and benefits of participating?
Participants will undergo a range of tests to discover their risk of developing cardiovascular and other chronic diseases. There are no expected risks in participating, except a small risk of bruising from giving the blood sample.

Where is the study run from?
The study is conducted by Bio-Competence Centre of Healthy Dairy Products, Estonia.

When is the study starting and how long is it expected to run for?
The study started in February 2012 and will run until December 2014.

Who is funding the study?
Archimedes Foundation of Ministry of Science and Education, Estonia and University of Tartu, Estonia.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
210/T-3

Study information

Scientific Title
Effect of kefir containing probiotic L. fermentum ME-3 on blood indices of healthy volunteers in a randomized double-blinded controlled parallel-designed two-armed study

Study objectives
The consumption of kefir with probiotic L. fermentum ME-3 helps to improve the indices of serum lipids and oxidative stress markers in pre-selected healthy individuals with borderline values of blood triglycerides, cholesterol and its fractions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Review Committee, University of Tartu, 19/12/2011, ref.: 210/T-3

Study design
Randomized double-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)
Other

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 values of blood triglycerides, blood cholesterol and its fractions

Interventions
Blocked randomization lists were produced by the statistician and held centrally.

The consumption of a probiotic kefir comprising Lactobacillus fermentum strain ME-3: daily dose of kefir 200 ml, daily dose of probiotic: 8x10^9 colony forming units for 8 weeks vs consumption of control kefir 200 ml. The participants provided blood samples four times: at selection, at the start and after 4 and 8 weeks; stool and urine samples were collected three times: at the start and after 4 and 8 weeks of intervention.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Cardiovascular health:
1. Significant decrease of LDL-cholesterol
2. Significant decrease of triglycerides

Protection against oxidative damage:
1. Significant decrease of oxidized LDL
2. Significant decrease of urinary isoprostanes

Secondary outcome measures

Cardiovascular health:
In probiotic group maintenance or significant reduction ($p<0.05$) of:
1. HDL-cholesterol
2. Homocysteine
3. ApoB/apoA1
4. hs-CRP
5. Leptin
6. Adiponectin
7. Blood pressure

Protection against oxidative damage:
In probiotic group maintenance or significant reduction ($p<0.05$) of:
1. Oxidative stress index (OSI)
2. Glutathione redox status (GSSG/GSH)
3. MPO
4. IL-6
5. TNF-alpha

Temporal colonization of GI tract with L. fermentum ME-3 detected in faecal samples.

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

Overall study start date
01/02/2012

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. A written informed consent
2. Age between 35 and 65 years
3. No known health problems
4. Elevated levels of blood total cholesterol/cholesterol fractions: >3.4 mmol/l for LDL, >3.0 mmol/l for the LDL/HDL ratio, >5.2 mmol/l for the total cholesterol and >1.7mmol/l for the 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

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Pregnancy and breastfeeding
2. A history of gastrointestinal disease, food allergy, diabetes
3. Acute infection within the last 2 weeks prior to enrolment
4. 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
5. Intolerance to the investigational product / its ingredients
6. Any kind of concurrent disease which could influence the evaluation of the efficacy and the tolerability of the investigational study product
7. Any serious organ or systemic diseases
8. High blood pressure (e.g. >140/95 mm Hg)
9. Eating disorder
10. Extensive exercise
11. Genetic hyperlipidemia
12. Drug or alcohol abuse
13. Active weight loss > 5 kg in prior 3 months
14. Participation in other studies within the last 30 days / during the study

Date of first enrolment
01/02/2012

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Estonia

Study participating centre
University of Tartu
Tartu
Estonia
50411

Sponsor information

Organisation

Tere AS (Estonia)

Sponsor details
Pärnu mnt 139c
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Sponsor type
Industry

Funder(s)

Funder type
Government

Funder Name
Archimedes Foundation of Ministry of Science and Education (Estonia)

Funder Name
University of Tartu (Estonia) - Faculty of Medicine, Dept. of Microbiology and Dept. of Biochemistry

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	results	01/12/2015		Yes	No