ISRCTN55339917 https://doi.org/10.1186/ISRCTN55339917

Effect of novel probiotic food supplement on elevated cardiometabolic and inflammatory markers on clinically asymptomatic volunteers.

Submission date
30/10/2014

Recruitment status
No longer recruiting

Registration date
12/03/2015

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English Summary
Background and study aims
Reg'Activ Cholesterol is a food supplement containing the probiotic lactobacillus fermentation ME-3. This probiotic is an antioxidant that has been shown to reduce oxidative stress, inflammation and cholesterol and has beneficial effects on blood glucose levels. The aim of this study is further to investigate further the effects of the Reg'Activ Cholesterol.

Who can participate?
Adults without clinical health problems, aged between 40-70 years and with high blood triglyceride and cholesterol levels

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (experimental group) are given Reg'Activ Cholesterol capsules for 8 weeks. Those in group 2 (control) are given a placebo for 8 weeks. Blood samples are taken from all participants at the start of the study and then after 4 and 8 weeks. These samples are analysed for blood cholesterol, triglyceride, and glucose levels and also for biomarkers of inflammation.

What are the possible benefits and risks of participating?
The benefit of participating in this study is that it may have health benefits for participants. There are no expected risks in participating. There is a small risk of bruising from giving a blood sample.

Where is the study run from?
University of Tartu (Estonia)

When is the study starting and how long is it expected to run for?
October 2014 to March 2015.

Who is funding the study?
1. University of Tartu, Faculty of Medicine, Department of Biochemistry (Estonia)
2. GIE Eurasante (France)

Who is the main contact?
1. Professor Mihkel Zilmer (University of Tartu)
2. Professor Tiiu Kullisaar (University of Tartu)

Contact information

Type(s)
Scientific

Contact name
Dr Tiiu Kullisaar

Contact details
Ravila str 19, Dept Biochemistry
Tartu
Estonia
50411

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
237/M-15

Study information

Scientific Title
Effect of novel probiotic food supplement on elevated cardiometabolic and inflam¬matory markers on clinically asymptomatic volunteers (a randomized blinded study).

Study hypothesis
The consumption of novel probiotic food supplement (RegActiv Cholesterol) compromising L. fermentum strain ME-3 helps to improve serum cardiometabolic and inflammatory markers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Review Committee, University of Tartu, 19/05/2014, ref: 237/M-15

Study design

Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
A written informed consent

Condition
Elevated values of blood lipids, oxidative stress, inflammation and blood glucose related indices.

Interventions
The consumption of a food supplement RegActiv Cholesterol: daily dose two capsules for 4 and 8 weeks vs consumption of control capsules

Intervention Type
Supplement

Primary outcome measure
1. LDL cholesterol
2. Triglycerides
3. Glycated hemoglobin
4. Oxidized LDL
5. Isoprostanes
Measured at baseline, at 4th week from the beginning of the trial, 8th week from the beginning of the trial.

Secondary outcome measures
1. HsCRP
2. Homocysteine
3. IL-6
4. TG/HDL ratio
5. Oxidative stress index
6. Proinflammatory cytokines
7. Adiponectin
8. Antiinflammatory cytokines
Measured at baseline, at 4th week from the beginning of the trial, 8th week from the beginning of the trial.

Overall study start date
10/10/2014

Overall study end date
31/03/2015

Eligibility

Participant inclusion criteria
1. A written informed consent
2. Aged between 40 - 70 years
3. No known health problems
4. Total cholesterol higher than 5.3 mmol/L or LDL-chol higher than 3.0mmol/L or triglycerides higher than 1.7 mmol/L or total cholesterol/HDL higher than 4 or LDL/HDL higher than 3 or glycated Hb higher than 5.7% or hsCRP higher than 1,0 mg/L or homocysteine higher than 11 micromol/L
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, vitamins, soy protein, psyllium seed husk or probiotics/prebiotics within the preceding at least 3 weeks
6. Willingness to maintain a stable diet and physical activity level

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
At least 50

Total final enrolment
45

Participant exclusion criteria
1. Pregnancy and breastfeeding
2. History of gastrointestinal disease
3. Food allergy
4. Diabetes
5. Acute infection within the last 3 weeks prior to enrolment
6. Use of any antimicrobial agents within the preceding 2 months
7. Use of any regular concomitant medication including any non-steroidal anti-inflammatory drugs and antioxidant products 3 weeks
8. Intolerance to the investigational product / its ingredients
9. Any kind of concurrent disease which could influence the evaluation of the efficacy
10. Tolerability of the investigational study product
11. Any serious organ or systemic diseases
12. Eating disorder
13. Extensive exercise

14. Genetic hyperlipidemia
15. Drug or alcohol abuse
16. Active weight loss > 5 kg in prior 3 months participation in other studies within the last 30 days /
during the study

Recruitment start date
10/10/2014

Recruitment end date
31/03/2015

Locations

Countries of recruitment
Estonia

Study participating centre
Ravila str 19, Dept Biochemistry
Tartu
Estonia
50411

Sponsor information

Organisation
GIE Eurasanté (France)

Sponsor details
310 rue Eugene Avinee
Loos-lez-Lille
France
59120

Sponsor type
Research organisation

ROR
https://ror.org/0165tjs71

Funder(s)

Funder type

University/education

Funder Name
University of Tartu, Faculty of Medicine, Department of Biochemistry (Estonia)

Funder Name
GIE Eurasanté (France)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2018 abstract in https://www.longdom.org/proceedings/complex-approach-to-cardiovascular-risk-profile-with-a-food-supplement-41665.html

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	28/10/2016	17/12/2020	Yes	No