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# 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 of protocol

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
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# 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 objectives
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

## Health condition(s) or problem(s) studied
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

### Completion date
31/03/2015

# Eligibility

### Key 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

### Key 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

### Date of first enrolment
10/10/2014

### Date of final enrolment
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 |