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A study to investigate the effect of probiotics in combination with fish oil on metabolic risk factors in overweight and obese subjects following caloric restriction diet

Submission date
02/03/2018

Recruitment status
No longer recruiting

Registration date
21/03/2018

Overall study status
Completed

Last Edited
24/01/2019

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
Hypercholesterolaemia (high blood cholesterol) is one of the risk factors for cardiovascular (heart) disease. Probiotics are live bacteria and yeasts promoted as having various health benefits. There is a growing evidence that some probiotic organisms lower cholesterol and may contribute to disease prevention. This study assesses the effect of probiotics in combination with fish oil on blood lipids (fats) and other markers of cardiovascular risk in obese and overweight adults following a calorie restricted diet.

Who can participate?
Overweight and obese adults aged 18 and over

What does the study involve?
Participants are randomly allocated to take either probiotics in combination with fish oil or placebo (dummy) capsules for 12 weeks. All participants are on a calorie restricted diet for 8 weeks followed by their standard diet for 4 weeks. Participants provide blood samples and their body composition is measured at the start of the study and after 8 and 12 weeks. Participants also complete food and health diaries.

What are the possible benefits and risks of participating?
Participants who receive probiotics in combination with fish oil may benefit from the improvement of their lipid profile and reduction of metabolic risk factors. There are no known risks to participants. Participants with food allergy or intolerance to any of the product components are excluded.

Where is the study run from?
Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry, Comenius University, Bratislava (Slovakia)

When is the study starting and how long is it expected to run for?
May 2015 to April 2016

Who is funding the study?
Cultech Ltd (UK)

Who is the mail contact?
Assoc. Prof. Jana Muchova, PhD

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V1.0

Study information

Scientific Title
A study to investigate the effect of probiotics in combination with fish oil on metabolic risk factors in overweight and obese subjects following caloric restriction diet

Acronym
ProWL

Study objectives

The study aims to investigate the impact of a probiotic and fish oil combination on lipid subfractions and cardiovascular risk factors in overweight and obese subjects following 8 weeks calorie restricted diet.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical committee of Medical School, Comenius University in Bratislava, Slovakia, 14/04/2015

Study design
Randomised double-blind placebo-controlled study

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 patient information sheet

Health condition(s) or problem(s) studied
Probiotic and fish oil combination on lipid subfractions and cardiovascular risk factors

Interventions
Participants randomised to active or placebo group will be required to take two capsules twice a day for 12 weeks:
1. Active intervention: Lab4p probiotic consortium capsule (L. acidophilus CUL60, L. acidophilus CUL21, L. plantarum CUL66, B. bifidum CUL20 and B. lactis CUL34) at 10×10^10 cfu per day and fish oil capsule containing 1 500 mg of a total omega 3 fatty acids per day
2. Placebo intervention: maltodextrin and sunflower oil capsules

All participants will be on a calorie restricted diet for 8 weeks followed by their standard diet for 4 weeks. Participants will provide venous blood samples and body composition measurements at baseline, 8 and 12 weeks. Participants will need to complete food and health diaries.

Intervention Type
Supplement

Primary outcome measure
1. Blood lipid profile (total cholesterol, LDL cholesterol, HDL, triacylglycerols), glucose, insulin and hsCRP levels are measured using the ADVIA 1800 Chemistry System at baseline, 8 and 12 weeks

2. HDL and LDL subfractions are determined using the Lipoprint® LDL and HDL systems at baseline, 8 and 12 weeks
3. Body composition measurements are determined using the InBody 230 at baseline, 8 and 12 weeks

Secondary outcome measures
1. Systolic and diastolic blood pressure are measured using blood pressure monitor at baseline, 8 and 12 weeks
2. Markers of oxidative stress, hormones and vitamins are determined by HPLC or ELISA assays at baseline, 8 and 12 weeks

Overall study start date
01/05/2015

Completion date
01/04/2016

Eligibility

Key inclusion criteria
1. Adults aged ≥ 18 years
2. BMI between 25 to 35 kg/m2
3. Participants are willing to give written informed consent
4. Participants who are willing to follow the caloric restricted diet for 8 weeks of the study period
5. Participants who are willing to avoid the use of other weight loss products during the study period
6. Participants who are willing to provide blood samples
7. Participants who are willing to avoid other probiotic, fish oil or oily fish use for the duration of the study

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 participants

Key exclusion criteria
1. Participants who have BMI ≤ 24.9 kg/m2 and ≥ 36 kg/m2
2. Participants who are unable/unwilling to give written informed consent
3. Participants who are not prepared to provide blood samples as required
4. Participants with known or suspected food allergy or intolerance to one of the intervention

products' components.
5. Participants who refuse to stop taking any probiotics supplements, dairy probiotic product (yoghurt with biocultures, Acidophilus milk, kefir, Actimel, Yakult, etc) and omega 3/fish oil supplements apart from the intervention products during the study period
6. Participants who have undergone bariatric surgery
7. Participants with three months of weight instability before study enrolment or known history of eating disorders (anorexia nervosa, bulimia nervosa)
8. Participants with diabetes mellitus 1st and 2nd type
9. Participants with personal history of severe chronic diseases (cancer, HIV, kidney failure, liver damage, diagnosed gastrointestinal disorders, arthritis, chronic respiratory failure, etc)
10. Pregnant or breastfeeding women or intending to become pregnant within next 3 months
11. Participants who had taken antibiotics within 4 weeks prior to enrolment
12. Participants with alcohol intakes > 14 units/week or 3 units/day
13. Participants fitted with any electronic implantable device (contraindicated for bioelectrical impedance analysis)

Date of first enrolment
08/09/2015

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Slovakia

Study participating centre
Comenius University
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Sponsor information

Organisation
Cultech Ltd

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Sponsor type
Industry

Website
http://www.cultech.co.uk

ROR
https://ror.org/00555bk04

Funder(s)

Funder type
Industry

Funder Name
Cultech Ltd (UK)

Results and Publications

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

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Assoc. Prof. Jana Muchova, PhD

IPD sharing plan summary
Available on request