

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

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Registration date 21/03/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/01/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Institute of Medical Chemistry, Biochemistry and Clinical Biochemistry, Medical School

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Sponsor information

Organisation

Cultech Ltd

ROR

<https://ror.org/00555bk04>

Funder(s)

Funder type

Industry

Funder Name

Cultech Ltd (UK)

Results and Publications

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