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Can taking probiotics ('friendly' bacteria) improve metabolic health and wellbeing in people who are overweight or obese?

Submission date
04/03/2019

Recruitment status
No longer recruiting

Registration date
12/03/2019

Overall study status
Completed

Last Edited
19/05/2023

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
Probiotics are ‘friendly bacteria’ that are known to improve health in human beings by, amongst other ways, interacting with the bacteria that already live in the gut. The aim of this study is to see if the daily consumption of a probiotic supplement can improve metabolism and general wellbeing in overweight and obese people.

Who can participate?
Adults aged between 30 to 65 years with a waist circumference of >89 cm (women) or >100 cm (men) and a body mass index (BMI) between 25 and 34.9.

What does the study involve?
The study is called a double-blind study which means that participants will be randomly assigned to take a capsule containing either the active product (the probiotic) or an identical inactive product (the placebo) every day for 180 days. There will be an equal chance for the participant to be assigned to take active or placebo with neither the participant or research staff aware of who is taking what. During the trial, the participants will also be asked to complete a series of questionnaires (relating to their general well-being and health) and provide blood samples and stool samples (optional) at beginning and end of trial.
After enrolment to the study, participants are asked to complete a general wellbeing questionnaire, undergo body measurements (e.g. weight, height, waist circumference and blood pressure), provide a fasting blood sample and a stool sample (which is optional and may be done at home if necessary). Participants will then be randomly assigned to receive capsules containing either the placebo (dummy) or probiotic that are to be taken every day for the following 180 days. During the study, participants will also be asked to record the occurrence of any symptoms they experience on a symptom diary and revisit the trial centre on day 90 and the end of the study (day 180) in order to complete wellbeing questionnaires, undergo body measurements and provide blood and/or stool samples. At the end of the study, scientists will use the information and samples collected to determine if there was any benefit to taking the probiotic supplement.

What are the possible benefits and risks of participating?
It is considered that the daily intake of the probiotics will improve quality of life and wellbeing and will also provide benefits related to metabolism (all the chemical processes that occur within the human body in order to maintain life) although, due to the chance that the participant may receive the placebo, it is perceived that these benefits will be confined to the participants who are randomly assigned the intervention. Participation in the study will bring more information and will improve our understanding of the benefits of daily probiotic supplementation.
There have been no adverse reactions associated with the probiotic product but participants may experience mild side effects such as a change in bowel habit and/ or increased flatulence (intestinal gas) during the first few days of taking the supplement.

Where is the study run from?
The trial is managed and will take place at the Medical Center 'Comac Medical' in Sofia, Bulgaria.

When is the study starting and how long is it expected to run for?
May 2017 to July 2018

Who is funding the study?
Cultech Ltd (UK)

Who is the main contact?
Dr Daryn Michael
darynm@cultech.co.uk

Contact information

Type(s)
Scientific

Contact name
Dr Daryn Michael

ORCID ID
http://orcid.org/0000-0001-8546-1153

Contact details
Cultech Ltd,
Unit 2 Christchurch Road
Baglan Industrial Estate
Port Talbot
United Kingdom
SA12 7BZ
01639 825100
darynm@cultech.co.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PROMAGEN_Version 0.1

Study information

Scientific Title
The impact of PRobiotics On Metabolic status And GENeral well-being in an overweight population (PROMAGEN)

Acronym
PROMAGEN

Study objectives
Daily probotic supplementation would positively benefit metabolic status and general well-being.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/06/2017 Ethics committee at MC "Comac Medical" (South Side Business Centre, 38 Maystor Aleksi Rilets Str (5th floor), Manastirski Livadi, West 1618 Sofia, Bulgaria; +359 2 892 10 00; clients@comac-medical.com), ref: 112/20.06/2017

Study design
Single-centre randomised double-blind placebo-controlled parallel-group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request participant information sheet.

Health condition(s) or problem(s) studied
Effects of probiotic supplementation on healthy overweight and obese individuals

Interventions
The active product contains Lactobacillus acidophilus CUL60 (NCIMB 30157), Lactobacillus acidophilus CUL21 (NCIMB 30156), Lactobacillus plantarum CUL66 (NCIMB 30280), Bifidobacterium bifidum CUL20 (NCIMB 30153) and Bifidobacterium animalis subsp lactis CUL34 (NCIMB 30172) at a total of 50 billion cfu per day.

The placebo contains microcrystalline cellulose.

Trial subjects were allocated in a 1:1 ratio into two parallel study arms (active arm or placebo arm) according to a randomisation protocol provided by an independent statistician. The intervention comprised a daily dose of active product that contained 50 billion bacteria (Lactobacillus acidophilus, Lactobacillus plantarum, Bifidobacterium bifidum and Bifidobacterium animalis subsp lactis) or a daily dose of placebo that did not contain any bacteria and was identical in appearance to the active product. The intervention period was 180 days.

Intervention Type
Supplement

Primary outcome measure
1. Plasma total cholesterol at baseline (day 0) and day 180
2. Plasma HDL-cholesterol at baseline (day 0) and day 180
3. Plasma LDL-cholesterol at baseline (day 0) and day 180
4. Plasma triacylglycerol at baseline (day 0) and day 180
5. Body weight measured on scales at days 0, 90 and 180
6. Waist circumference measured by tape at baseline (day 0) and day 180
7. Blood pressure measured by a blood pressure monitor at days 0, 90 and 180
The methods of analysis for the blood and faecal tests have yet to be finalised.

Secondary outcome measures
1. General well-being assessed using a quality of life questionnaire at days 0, 90 and 180
2. Gastrointestinal symptoms, such as diarrhoea, constipation, abdominal pain, vomiting, bloating, nausea and infection, recorded daily throughout the intervention period using a daily symptom questionnaire
3. Microbiota composition/functionality assessed using next-generation sequencing (NGS) and /or microbial culture at days 0 and 180
4. Plasma inflammatory markers (C-reactive protein [CRP]) at days 0 and 180
5. Faecal and plasma bile concentration (total, conjugated and deconjugated) at days 0 and 180
The methods of analysis for the blood and faecal tests have yet to be finalised.

Overall study start date
23/05/2017

Completion date
23/07/2018

Eligibility

Key inclusion criteria
1. Aged between 30 and 65 years at stage 1
2. Waist circumference >89 cm (women) or >100 cm (men) at stage 1

3. Body mass index (BMI) between 25 and 34.9 kg/m2 at stage 1
4. Willing to provide blood samples at stage 1 and stage 3
5. No statin treatment or on stabilised statin therapy (at least 3 months intake before stage 1)

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
220

Total final enrolment
220

Key exclusion criteria
1. Immunodeficiency or ongoing immunosuppressive therapy
2. Diagnosed diabetes
3. Pregnant or planning pregnancy
4. Anamnesis of ischemic heart disease, heart failure, prolonged QTc interval, rhythm and conduction disorders, e.g. absolute arrhythmia, ventricular extrasystole, atrioventricular block or any other cardiovascular disease deemed by the investigator as a risk for the participation in the study
5. Severe systemic disease (cancer, dementia, advanced organ failure)
6. Weight loss in the last 3 months prior to stage 1, which cannot be explained with a dietary regimen or increased physical activity

Date of first enrolment
17/07/2017

Date of final enrolment
26/07/2017

Locations

Countries of recruitment
Bulgaria

Study participating centre
Comac Medical
South Side Business Centre
38, Maystor Aleksi Rilets Str., 5th fl.
Res. Distr. Manastirski Livadi – West

Sofia
Bulgaria
1618

Sponsor information

Organisation
Cultech Ltd

Sponsor details
Unit 2 Christchurch Road,
Baglan Industrial Estate,
Baglan
Port Talbot
United Kingdom
SA12 7BZ
01639 825100
suep@cultech.co.uk

Sponsor type
Industry

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

ROR
https://ror.org/00555bk04

Funder(s)

Funder type
Industry

Funder Name
Cultech Ltd

Results and Publications

Publication and dissemination plan
Results will be published in a peer-reviewed scientific journal.

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	05/06/2020	Yes	No
Results article	Further analysis	25/03/2021	19/05/2023	Yes	No