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Can changing the structure of fat in a meal improve risk factors for cardiovascular disease?

Submission date
08/01/2020

Recruitment status
No longer recruiting

Registration date
13/01/2020

Overall study status
Completed

Last Edited
07/06/2023

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
We know that poor lifestyles, including the food we eat, can increase the risk of developing cardiovascular disease. One area of research that has received little attention, is whether changing the amount and structure of fat in food can influence cardiovascular disease risk factors. This study assesses whether changing the amount and structure of fat in food can influence a range of cardiovascular risk factors, including the presentation of fat in the blood. High amounts of fat in the blood has been shown to increase the risk of cardiovascular disease. The study is being carried out by researchers from the School of Food Science and Nutrition and the Leeds Institute of Genetics, Health and Therapeutics at the University of Leeds.

Who can participate?
Healthy adults aged 18 to 70 years.

What does the study involve?
Participants will be assessed for eligibility against set criteria. This will involve asking questions about lifestyle, age, medical issues any treatment or medication.

After confirming eligibility, participants will attend three laboratory visits commencing on a morning-time (between 08:00 and 09:00 AM), with each visit separated by at least 3 days.

During the course of 24-hours prior to the first visit to the laboratory, participants will record diet and physical activity patterns by logging information into an online programme. Participants will list individual food items consumed during this time and describe items in as much detail as possible (i.e. the size of the portion, time of eating, cooking methods), retaining packaging and nutritional information where possible. During this time, participants will be required to abstain from drinking alcohol, caffeinated drinks and foods, paracetamol and drugs containing paracetamol, as well as strenuous physical activity. Participants will also be provided with a meal, which will serve as their evening, and last, meal of that day. This meal will be comprised of a vegetarian pasta dish with a side of green vegetables. Participants will be required to follow the cooking instructions on the packaging of these foods and note down the time at which they eat them. After they have eaten this meal, participants will abstain from eating or drinking anything else other than water for the remainder of the night. Participants will be asked to replicate

eating patterns (the type, amount and timing of food) and physical activity before each visit to the laboratory.

On each visit to the laboratory, participants will be required to arrive in a fasted state; i.e. having not consumed anything other than water after their evening meal and having skipped breakfast. Once participants have arrived at the laboratory, measurements such as height and weight, and blood pressure will be taken. After these measures have been taken, participants will assume a seated position whilst a small cannula is inserted into an arm on the reverse of the elbow. Once an initial blood sample has been taken, participants will consume a meal. The meal will be a curry-based dish served with rice. The meals consumed on each visit to the laboratory will look and taste identical, but will differ in the amount of fat, and the structure of fat, such that on each occasion participants will eat a meal which is either:
1. Low in fat
2. High in fat
3. High in fat (differing in fat structure)

Participants will consume the meal within a 20-minute period. Further blood samples will be taken at regular 30-minute intervals for up to 4-hours. The total number of samples taken will be 9, and the total amount of blood taken across the duration of each visit will be 135ml which is equivalent to approximately one third of a soft drinks can. After the last blood sample has been taken, the cannula will be removed and the participant will be free to leave to the laboratory. Each of the three visits will be identical in procedures (i.e. timing, blood sampling), and differing only in the composition of the food eaten.

What are the possible benefits and risks of participating?
By participating in this study participants will be contributing to internationally leading research on the understanding of cardiovascular risk. We cannot promise that the study will definitely help those who participate, but their results, and the results from other participants may help to provide a better understanding of how the amount and structure of fat in meals can impact the health of the heart and blood vessels.

We will ask participants to complete an initial screening telephone interview to establish whether the study procedures pose any risk to their health. However, as with all research, there are always some potential risks participants should be aware of.

Taking blood from a vein can sometimes cause discomfort and may result in some minor bruising and soreness. All blood samples will be taken by a trained and experienced phlebotomist to ensure safety and minimise discomfort. Participants will be invited into the study only if they satisfy all of the study safety eligibility criteria. As we are using commercially available food products and preparing food items in our controlled nutritional kitchen, we do not anticipate any adverse effects to eating the foods provided.

Where is the study run from?
School of Food Science and Nutrition at the University of Leeds

When is the study starting and how long is it expected to run for?
Recruitment to the study began 12/06/2019 and will run until 10/11/2019.

Who is funding the study?
University of Leeds, Zhejiang Gongshang University, Nutricia Research Foundation, Wellcome Trust and Biotechnology and Biological Sciences Research Council have all contributed to funding for this study.

Who is the main contact?
Dr Matthew Campbell, School of Food Science and Nutrition, University of Leeds m.d.campbell@leeds.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MEEC 18-039

Study information

Scientific Title
Impact of manipulating lipid droplet size of high-fat meals on postprandial clinical parameters

Study objectives
Manipulation of the lipid-droplet size will differentially impact postprandial parameters of cardiometabolic health. Configuration to a fine/small lipid droplet size will result in a more pronounced postprandial lipaemic response.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 11/07/2019, MaPS and Engineering joint Faculty Research Ethics Committee (The Secretariat University of Leeds, Leeds, LS2 9JT; +44 01133431642; MEECResearchEthics@leeds.ac.uk), ref: MEEC 18-039

Study design
Single centre, randomised, interventional trial. Double-blind, cross-over, counter-balanced design.

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Lipid metabolism

Interventions
Randomisation process was via an online computer programme into 3 intervention arms.
3 oral lipid tolerance tests, with each differing in the amount of fat, or fat structure.
Treatment 1: Consumption of a mixed-macronutrient meal with a low-fat content.
Treatment 2: Consumptions of a mixed-macronutrient meal with a high-fat content with large /corse lipid droplet size/composition.
Treatment 3: Consumptions of a mixed-macronutrient meal with a high-fat content with small /fine lipid droplet size/composition.
Total duration of each interventional arm was 48-hours repeated weekly over a 3-week period without further follow-up.

Intervention Type
Procedure/Surgery

Primary outcome measure
Response to oral fat intake measured by blood triglyceride incremental Area Under the Curve (iAUC) from 0 to 360 minutes postprandially.

Secondary outcome measures
Changes in cardiometabolic parameters (Platelet function and reactivity, cholesterol, lipoprotein and lipoprotein subclasses, and insulin) in response to oral fat intake measured by in whole blood and blood plasma via flow cytometry, an enzymatic method, ELISA, radioimmunoassay assessed from 0 to 360 minutes postprandially.

Overall study start date
01/02/2019

Completion date
11/12/2019

Eligibility

Key inclusion criteria
1. 18-70 years
2. Understanding of written English and ability to provide written informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
18

Total final enrolment
16

Key exclusion criteria
1. Diagnosis, or current treatment, for issues relating to gut mobility or digestion
2. Diagnosis, or current treatment, for a haematological disorder
3. History of deep vein thrombosis
4. Heart attack or stroke ≤6 months prior to recruitment
5. History of, or current, malignancy
6. Pregnancy
7. Amenorrhoea or menopause
8. Allergies or dietary intolerances likely to be exacerbated by study procedures
9. Medical or psychiatric conditions likely to interfere with the study, as determined by the study investigator

Date of first enrolment
12/06/2019

Date of final enrolment

10/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
School of Food Science and Nutrition
University of Leeds
Leeds
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LS14 1DB

Sponsor information

Organisation
University of Leeds

Sponsor details
The Secretariat
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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type

University/education

Funder Name
University of Leeds

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Zhejiang Gongshang University

Alternative Name(s)
ZJSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
China

Funder Name
Nutricia Research Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Biotechnology and Biological Sciences Research Council

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Data will be composed and presented for dissemination and publication at scientific meetings and peer-reviewed journals in 2020.

Intention to publish date
01/05/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be publicly available upon request from Dr Matthew Campbell [matthewcampbell.sunderland.ac.uk), in anonymised raw form, after the date of publication and for a duration of 3 years. All requests for data should be accompanied with a research proposal which will be reviewed by the institutional ethics committee prior to any decision to release data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		16/02/2021	16/02/2021	No	No
Results article		02/07/2021	06/07/2021	Yes	No