ISRCTN13406789 https://doi.org/10.1186/ISRCTN13406789

Postprandial cheese matrix study

Submission date	Recruitment status	[ ] Prospectively registered
08/02/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/02/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/08/2019	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Recent studies show that foods of the same overall nutrient composition but eaten in different food structures result in different digestive effects, and subsequently different health effects. This is becoming known as the food matrix effect. Dairy foods are a particular example of this effect. A number of studies have shown that dairy fat eaten in the form of cheese has a lower cholesterol-increasing effect compared to the same fat eaten as butter, even when the other nutrients, such as protein and calcium, are controlled for. There are lots of theories about this, and evidence suggests that calcium and the type of protein may have an effect. Many of the studies are 6 weeks in length and look at the change in LDL cholesterol levels over time. However, LDL-cholesterol levels are just one factor for heart disease risk. Another factor is raised levels of circulating fatty acids after eating, known as post-prandial lipaemia. The aim of this study is to look at what happens in the hours after eating dairy fat in three different forms: as cheese, as a reduced fat cheese plus butter, and as butter, protein and calcium. It is thought that the cheese 'matrix' will result in lower circulating fatty acids compared to butter, and that the cheese and butter will give a result somewhere in between.

Who can participate?
Healthy volunteers

What does the study involve?
Participants eat three meals in a random order with a 5-7 day break in between meals. Meal 1 is 120g full fat cheddar cheese and a slice of low-fibre white toast. Meal 2 is 120g reduced fat cheddar cheese and a slice of low-fibre white toast. Meal 3 is 30g calcium caseinate powder. Circulating fatty acids and blood glucose are measured from blood samples collected at fasting, and hourly, on the hour, for the 6-hour period after eating.

What are the possible benefits and risks of participating?
There are no known benefits to participating. Potential risks are discomfort or bruising from the blood sampling, and the risk of finding the study food unpleasant.

Where is the study run from?
University College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
February 2018 to August 2018

Who is funding the study?
Enterprise Ireland

Who is the main contact?
Dr Emma Feeney

Contact information

Type(s)
Scientific

Contact name
Dr Emma Feeney

Contact details
UCD Centre for Molecular Innovation and Drug Discovery
Science Centre South, Belfield
Dublin
Ireland
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LS-17-103

Study information

Scientific Title
Post-prandial randomised controlled trial to examine the postprandial effects of dairy fat within different matrices

Study objectives
Dairy fat, when eaten in varying levels of a cheese matrix, will have different outcomes on postprandial lipids.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Committee in University College Dublin, 24/01/2018, ref. LS-17-103

Study design
Single-centre randomised cross-over intervention trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

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
Blood lipids

Interventions
Subjects will receive three meals which contain dairy fat in varying levels of a cheese matrix, with a slice of toast as a carrier, in a random order with a 5-7 day washout period in between meals. Due to the nature of the meals, the arms cannot be masked.

Arm 1: 120g full fat cheddar cheese and a slice of low-fibre white toast
Arm 2: 120g reduced fat cheddar cheese and a slice of low-fibre white toast
Arm 3: 30g calcium caseinate powder

Intervention Type
Other

Primary outcome measure
Circulating fatty acids measured with a Randox Daytona from blood samples collected at fasting, and hourly, on the hour, for the 6-hour postprandial period

Secondary outcome measures
Blood glucose measured with a Randox Daytona from blood samples collected at fasting, and hourly for the 6-hour post-prandial period

Overall study start date
01/02/2018

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Fasting triglycerides <2.5
2. BMI 18-35

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
8-10

Key exclusion criteria
1. Familial hypercholesteraemia
2. Fasting triglycerides greater than 2.5
3. Any diagnosed metabolic disorder such as diabetes type 1 or 2

Date of first enrolment
01/02/2018

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Science Centre South
Belfield
Dublin
Ireland
D04 V1 W8

Study participating centre
Food for Health Ireland
UCD Centre for Molecular Innovation and Drug Discovery

Science Centre South, Belfield
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Sponsor information

Organisation
Food for Health Ireland

Sponsor details
UCD Centre for Molecular Innovation and Drug Discovery
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+ 353 (0)17162391
fhi@ucd.ie

Sponsor type
Not defined

Website
www.fhi.ie

ROR
https://ror.org/01nvbq395

Funder(s)

Funder type
Government

Funder Name
Enterprise Ireland

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Publication and dissemination plan
The results will be prepared for publication and submitted to relevant journals in the field. Other additional documents will not be made available at this time.

Intention to publish date
31/08/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. The data will be stored on a password-protected computer (encrypted) as per UCD data protection recommendations.

IPD sharing plan summary
Not expected to be made available