

Postprandial cheese matrix study

Submission date 08/02/2018	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 16/02/2018	Overall study status Completed	☐ Protocol
Last Edited 08/08/2019	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

D04 V1 W8

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Single-centre randomised cross-over intervention trial

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

Completion date

31/08/2018

Eligibility

Key inclusion criteria

1. Fasting triglycerides <2.5
2. BMI 18-35

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Familial hypercholesterolemia
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

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Study participating centre

Food for Health Ireland

UCD Centre for Molecular Innovation and Drug Discovery

Science Centre South, Belfield

Dublin

Ireland

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Sponsor information

Organisation

Food for Health Ireland

ROR

<https://ror.org/01nvbq395>

Funder(s)

Funder type

Government

Funder Name

Enterprise Ireland

Alternative Name(s)

The Enterprise Ireland

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Ireland

Results and Publications

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