

Effect of high and low calcium in a cheese matrix

Submission date 07/07/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 12/07/2022	Overall study status Completed	
Last Edited 24/02/2023	Condition category Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

The aim of this study is to further our understanding of the effect of the cheese matrix on blood lipid (fat) profiles. Previous studies have observed that cheddar cheese consumption can result in a lowering of low-density lipoprotein (LDL) cholesterol ("bad" cholesterol). This is thought to occur through the calcium in cheese binding to the fat, reducing intestinal absorption and increasing faecal excretion. This may be specific to the form of the calcium present within the matrix of cheese, but this is not confirmed since other studies have used a variety of dairy foods and their matrices are all different, so it is not possible to test the effect of calcium alone from these studies. This study aims to find out whether increasing the calcium in a cheese matrix will increase the faecal fat excreted compared with a reduced calcium cheese, and the reduced calcium cheese plus a supplement.

Who can participate?

Healthy male volunteers aged 18-35 years with no known metabolic disease and with a body mass index (BMI) in the normal range

What does the study involve?

Volunteers will be given all of their food and drinks for three 2-week periods. They will keep a diary of this and anything they eat additional to what is provided. They will come to the intervention suites at UCD for weight and height measures, and give a blood sample at baseline, before and after each dietary period. During the last 5 days of each 2-week period, they will collect all their stool produced throughout the day, and it will be collected by the researchers once a day (three collection periods in total).

What are the possible benefits and risks of participating?

There are no known risks or benefits of participating. There may be some discomfort at the site of venepuncture when giving blood samples.

Where is the study run from?

University College Dublin (Ireland)

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

March 2016 to May 2018

Who is funding the study?

Enterprise Ireland

Who is the main contact?

Emma Feeney, emma.feeney@ucd.ie

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

LS-16-60-Feeney-Gibney

Study information

Scientific Title

Effect of low-calcium and high-calcium cheddar cheese consumption on the excretion of faecal fat – a 2-week cross-over dietary intervention study

Study objectives

Consuming calcium within the matrix of cheese increases faecal fat excretion compared to the same amount of calcium eaten as cheese plus a supplement.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/03/2016, UCD HREC (UCD Office of Research Ethics Roebuck Castle University College Dublin Belfield, Dublin 4, Ireland; +353 1 716 8767; no email provided), ref: LS-16-60-Feeney-Gibney

Study design

Single-centre interventional randomised cross over 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

Effect of cheese calcium on fat excretion and blood lipids

Interventions

A randomisation table was used and participants were randomised into a sequence to complete 3 conditions:

1. High calcium cheddar cheese (240 g/day) for 2 weeks
2. Reduced calcium cheddar cheese (240 g/day) for 2 weeks
3. Reduced calcium cheddar cheese (240 g/day) for 2 weeks + calcium supplement

It is not possible to blind participants due to the supplement.

Volunteers will be given all of their food and drinks for three 2-week periods. They will keep a diary of this and anything they eat additional to what is provided. They will come to the intervention suites at UCD for weight and height measures, and give a blood sample at baseline, before and after each dietary period. During the last 5 days of each 2-week period, they will collect all their stool produced throughout the day, and it will be collected by the researchers once a day (three collection periods in total).

Intervention Type

Other

Primary outcome measure

Faecal fat excretion rates (g/day) measured during the last 5 days of each period. All samples received are freeze-dried, and each 5-day sample for each participant is pooled and stored at room temperature. Faecal fat analysis, (and faecal fatty acid profiling) is conducted at the University of Aarhus Denmark, using a modified Bligh and Dyer technique for total fat (Bendsen et al., 2008).

Secondary outcome measures

1. Fasting levels of Total Cholesterol, HDL-Cholesterol and LDL-cholesterol (mmol/L), triglycerides (mmol/L), Non-Esterified Fatty Acid (NEFA) (mmol/L), C-reactive protein (ng/ ml) and glucose (mmol/L) measured at baseline, and post-intervention for each study condition. Total cholesterol, HDL, triglyceride, Non-Esterified Fatty Acid, C-reactive protein and glucose concentrations are all determined using a Randox RX Daytona Clinical Chemistry Analyser (Randox Laboratories Ltd, UK).
2. Waist circumference, in cm, and weight in kg measured at baseline and post-intervention

Overall study start date

16/03/2016

Completion date

24/05/2018

Eligibility

Key inclusion criteria

1. Healthy male volunteers
2. Aged 18-35 years
3. Normal range body mass index (BMI)
4. No known metabolic disease

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

35 Years

Sex

Male

Target number of participants

10

Total final enrolment

10

Key exclusion criteria

1. Female
2. Aged under 18 or over 35 years
3. BMI outside the normal range
4. Metabolic disease

Date of first enrolment

01/04/2017

Date of final enrolment

05/03/2018

Locations**Countries of recruitment**

Ireland

Study participating centre

University College Dublin
Institute of Food and Health
Belfield
Dublin
Ireland
D4

Sponsor information**Organisation**

University College Dublin

Sponsor details

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Sponsor type

University/education

Website

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ROR

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

Publication planned in a high-impact journal

Intention to publish date

01/09/2022

Individual participant data (IPD) sharing plan

Participant level data will not be available for sharing as per the data sharing statement in the ethics application

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/02/2023	24/02/2023	Yes	No