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Effect of high and low calcium in a cheese matrix

Submission date
07/07/2022

Recruitment status
No longer recruiting

Registration date
12/07/2022

Overall study status
Completed

Last Edited
24/02/2023

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
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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other

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(s)
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).

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
Male

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

ROR
https://ror.org/05m7pjf47

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

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