ISRCTN10490434 https://doi.org/10.1186/ISRCTN10490434

Grass-fed vs 100% Total Mixed Rations-fed whole milk powder on circulating levels of fatty acids and vitamins

Submission date
24/11/2023

Recruitment status
No longer recruiting

Registration date
29/11/2023

Overall study status
Completed

Last Edited
16/06/2025

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
Recent studies have demonstrated that grass-fed dairy foods (e.g. milk, butter, cream) provide a more favourable nutrient profile in terms of fatty acids and several antioxidants, in comparison to non-grass-fed dairy foods. However, previous studies have explored this in milk and cheese only. This considered, the beneficial effects of grass-fed dairy in the context of whole milk powder (WMP), in comparison to grain-fed WMP are unknown.
This study will explore the effect of grass-fed vs grain-fed WMP on circulating fatty acids, vitamins, and markers of metabolic health in a population of healthy adults aged 20-60 years. This research will help us to further understand how feeding regimes can affect dairy produce with the interest of improving the nutrient profile of dairy foods to improve health outcomes.

Who can participate?
Healthy volunteers aged 20-60 years who are not taking medication for cholesterol, blood pressure or digestion or following a prescribed diet e.g., for weight loss or cholesterol.

What does the study involve?
Following a short screening questionnaire, eligible participants will be asked to proceed with the following:
1. They will complete four visits in total to the UCD volunteer suite, completing two dietary intervention phases (6 weeks each), with a 4-week washout period between.
2. Initial visit – 20 minutes at the UCD Volunteer Suites (body composition measurements and a blood sample by a qualified nurse). Participants will be assigned to one of two test diets. WMP samples will be supplied in portioned packs, with instructions on how to consume daily for 6 weeks.
3. Second visit – this will be a repeat of the initial visit.
4. After the 4-week washout period, participants will return for their 3rd visit and repeat the same protocol as the previous visits. They will then be assigned the second test diet.
5. During each 6-week period – participants will keep records of their dietary intake, including calls with a trained nutritionist.
6. Final visit – this will be a repeat of the previous visits.

What are the possible benefits and risks of participating?
There are no known benefits of taking part. However, participants will be contributing to important research. There may be some slight discomfort in providing blood samples, but this will be done by trained and experienced professionals and will involve a small amount of blood (less than a blood donation). There is also a potential risk of tiredness after giving blood.

Where is the study run from?
Institute of Food and Health at University College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
February 2021 to December 2022

Who is funding the study?
Food for Health Ireland

Who is the main contact?
Prof. Eileen Gibney, eileen.gibney@ucd.ie

Study website
https://www.ucd.ie/foodandhealth/cheesestudy/

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof EIleen GIbney

ORCID ID
https://orcid.org/0000-0001-9465-052X

Contact details
UCD Institute of Food and Health
UCD Centre for Molecular Innovation
Science Centre South
University College Dublin
Belfield
Dublin
Ireland
D04 V1 W8
+353 (0)1 7162819
eileen.gibney@ucd.ie

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Emma Feeney

ORCID ID
https://orcid.org/0000-0003-3234-6340

Contact details
S2.16a Science Centre South
UCD Institute of Food and Health
Belfield
Dublin
Ireland
D04 V1 W8
+353 (0)17162247
emma.feeney@ucd.ie

Type(s)
Public

Contact name
Dr Martina Rooney

ORCID ID
https://orcid.org/0000-0002-5450-8737

Contact details
UCD Institute of Food and Health
UCD Centre for Molecular Innovation
Science Centre South
University College Dublin
Belfield
Dublin
Ireland
D04 V1 W8
None provided
martina.rooney@ucd.ie

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
FHI3 WMP

Study information

Scientific Title

Grass-fed vs 100% Total Mixed Rations-fed whole milk powder on circulating levels of fatty acids and vitamins

Study objectives
It is hypothesised that compared to total mixed rations-fed whole milk powder (WMP), grass-fed WMP will increase circulating concentrations of conjugated linoleic acid (CLA), n-3 and n-6 fatty acids.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/01/2022, UCD Office of Research Ethics (UCD Research, Tierney Building, Belfield, Dublin, D04 V1W8, Ireland; +353 (0)1 716 7777; research.ethics@ucd.ie), ref: LS-21-99-OConnor-Gibney

Study design
Single-centre double-blinded randomized controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
University/medical school/dental school

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Healthy adults

Interventions
A two-arm crossover trial, with 6-week intervention arms and a 4-week washout period. Participants were allocated to a sequence of treatment using an online randomisation tool (https://www.sealedenvelope.com). Participants were randomised to receive either 200 g/day of whole milk powder made from 100% grass-fed milk or 200 g/day whole milk powder made from 100% pasture-fed milk for 6 weeks. There was a 4-week washout period before participants received the second treatment. Participants could consume the powder as it is, or reconstitute with water, and participants were provided with recipes to incorporate the whole milk powder into their diet.

Intervention Type
Supplement

Primary outcome measure

Circulating levels of CLA, n-3 and n-6 fatty acids measured in blood samples by HPLC at baseline and 6 weeks

Secondary outcome measures
1. Total, HDL and LDL cholesterol, triglyceride and glucose concentrations measured in blood samples using NMR at baseline and 6 weeks
2. Insulin concentrations measured in blood samples using ELISA at baseline and 6 weeks
3. Blood pressure (diastolic and systolic blood pressure) assessed using an electronic blood pressure monitor at baseline and 6 weeks
4. Anthropometry assessed by measuring weight, BMI, body fat % and waist circumference at baseline and 6 weeks
5. Inflammatory markers (hs-CRP, IL2, IL10) assessed by biomarker status at baseline and 6 weeks
6. Antioxidant status (circulating ß-carotene, tocopherol, and retinol) as well as markers of lipid peroxidation biomarker F2-isoprostane assessed by biomarker status at baseline and 6 weeks

Overall study start date
01/02/2021

Completion date
16/12/2022

Eligibility

Key inclusion criteria
1. Healthy, not taking medication for cholesterol, blood pressure or digestion
2. Not following a prescribed diet for any reason (weight loss, cholesterol etc)
3. Free from dairy intolerance/allergy and consume an omnivorous diet
4. Male or female, aged 20 - 60 years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
20 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
48

Total final enrolment
54

Key exclusion criteria
1. Currently taking prescribed medication
2. Following any specific diet will be ineligible for participation in the study
3. Fatty acid/oil-based dietary supplements e.g., fish oils, omega3/6, and other herbal fatty acid-based supplements - e.g., evening primrose oil

Date of first enrolment
12/04/2022

Date of final enrolment
02/09/2022

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Food for Health Ireland
Science Centre South
Belfield
Dublin
Ireland
D04 V1W8

Study participating centre
Food for Health Ireland
UCD Centre for Molecular Innovation and Drug Discovery
Science Centre South
Belfield
Dublin
Ireland
D04 V1W8

Sponsor information

Organisation
Food for Health Ireland

Sponsor details
UCD Centre for Molecular Innovation and Drug Discovery
Science Centre South

Belfield
Dubin
Ireland
D04 V1 W8
+353 (0)1 716 2391
fhi@ucd.ie

Sponsor type
Research organisation

Website
https://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
Planned publication in high-impact peer-reviewed journal.

Intention to publish date
30/06/2025

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			28/11/2023	No	Yes
Results article		12/06/2025	16/06/2025	Yes	No