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

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------------------|--|--------------------------------|--|--|
| 24/11/2023 | | ☐ Protocol | | |
| Registration date 29/11/2023 | Overall study status Completed | Statistical analysis plan | | |
| | | [X] Results | | |
| Last Edited 16/06/2025 | Condition category Nutritional, Metabolic, Endocrine | [] 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

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

20 years

Upper age limit

60 years

Sex

All

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

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

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

Study outputs

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