

Effects of lipid composition and structure in meat and dairy foods on digestibility and low-grade inflammation in cells, animals and humans -Postprandial part

Submission date 25/10/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/10/2024	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 30/06/2025	Condition category Nutritional, Metabolic, Endocrine	<input checked="" type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This study aims to investigate how different types of animal fats from dairy and meat products affect feelings of fullness and hunger. Previous research has shown that saturated fats from these sources can negatively impact heart health. Since dairy and meat make up a significant portion of the Norwegian diet, this study will look at how these fats influence satiety (the feeling of being full).

Who can participate?

Healthy men and women aged 18 to 40 years, with normal body weight and less than 10 hours of physical activity per week, can participate in this study.

What does the study involve?

Participants will arrive fasting in the morning and receive one of two test breakfasts, which include either semi-hard cheese or pork sausage along with bread, tomatoes, and juice. Blood samples will be taken before and after the meal, and then every 30 to 60 minutes for up to 240 minutes. After this, participants can eat as much as they want from a buffet, and their food intake will be recorded. Participants will also rate their hunger, fullness, desire to eat, and prospective food consumption throughout the session. Four weeks later, participants will return to repeat the process with the other test meal.

What are the possible benefits and risks of participating?

Participants will contribute to important research that could improve understanding of how different fats affect satiety and overall health. There are minimal risks involved, mainly related to blood sample collection, such as slight discomfort or bruising.

Where is the study run from?

The study is conducted at The Norwegian University of Life Sciences (NMBU) in Norway.

When is the study starting and how long is it expected to run for?
September 2020 to July 2025

Who is funding the study?
The study is funded by The Norwegian Agriculture Agency.

Who is the main contact?
Prof. Bjørg Egelanddal (bjorg.egelanddal@nmbu.no).

Contact information

Type(s)

Public, Scientific

Contact name

Prof Bjørg Egelanddal

ORCID ID

<https://orcid.org/0000-0003-0877-4628>

Contact details

Postbox 5003 Christian Falsens vei 1

Ås

Norway

1433

+47 917 33 440.

bjorg.egelanddal@nmbu.no

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Milena Monfort-Pires

ORCID ID

<https://orcid.org/0000-0002-1652-8083>

Contact details

Turku University Hospital, Building 14,,

Kiinamylynkatu 4-8

Turku

Finland

20521

: +358 02 3130000

milenamomfort@gmail.com

Type(s)

Public, Scientific

Contact name

Prof Anna Haug

ORCID ID

<https://orcid.org/0000-0003-4704-699X>

Contact details

Arboretveien 6,
Faculty of Biosciences, NMBU
Ås
Norway
1433
+47 917 33 440.
anna.haug@nmbu.no

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

National Research Council: 281297; National ethic committee approval number: 139404

Study information

Scientific Title

Effects of meat and dairy fat and protein on human satiety markers (postprandial part)

Acronym

LIG-IN-two

Study objectives

To investigate how different animal fat sources (from cheese and pork) affect satiety.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 26/09/2020, The Norwegian National Research Ethics Committee, Regional Committees for Medical and Health Research Ethics (Kongens gate 14, Oslo, 0153, Norway; +47 (0)23 31 83 00; post@forskningsetikk.no), ref: 139404

Study design

Interventional randomized crossover clinical trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Health/metabolic effects of healthy diets with cheese and pork meat

Interventions

The study employs a crossover design with two different breakfast diets. To ensure equal distribution of all test diets, the experiment is structured as a Latin square design. Each diet is tested on separate days with a four-week interval between tests.

Participants receive a test meal for breakfast, which includes the test products (cheese and pork sausage) along with bread, tomatoes, and juice. The quantity of the test products in the breakfast is determined by their protein and fat content, with approximately 65-70% of the energy intake (E%) coming from these test products.

An Ad libitum buffet is provided, featuring bread slices cut into halves, offering participants half sandwiches. The toppings for these sandwiches are the participants' 2nd and 3rd choices from a pre-determined list presented to them in advance.

Intervention Type

Behavioural

Primary outcome(s)

1. Appetite is measured using Ad Libitum buffet, where participants are given 25 quarters of sandwiches with their 2nd and 3rd choice of fillings (cooked ham, cheese, mackerel in tomato sauce, or liver pate) on both experimental days
2. Energy intake is measured using Ad Libitum buffet and Norwegian Directorate of Health /Norwegian Food Safety Authority tool, where participants are given 25 quarters of sandwiches with their 2nd and 3rd choice of fillings (cooked ham, cheese, mackerel in tomato sauce, or liver pate) on both experimental days
3. Prospective food consumption is measured using Visual Analogue Scale (VAS) at fasting, 15', 30', 60', 90', 120', 180', 240', and after the Ad Libitum buffet
4. Fullness is measured using Visual Analogue Scale (VAS) at fasting, 15', 30', 60', 90', 120', 180', 240', and after the Ad Libitum buffet
5. Hunger is measured using Visual Analogue Scale (VAS) at fasting, 15', 30', 60', 90', 120', 180', 240', and after the Ad Libitum buffet
6. Desire to eat is measured using Visual Analogue Scale (VAS) at fasting, 15', 30', 60', 90', 120', 180', 240', and after the Ad Libitum buffet
7. CCK (pmol/L) is measured using blood tests at seven timepoints during one session
8. Ghrelin (pg/ml) is measured using blood tests at seven timepoints during one session
9. GIP (pg/ml) is measured using blood tests at seven timepoints during one session
10. GLP-1 (pg/ml) is measured using blood tests at seven timepoints during one session
11. Leptin (pg/ml) is measured using blood tests at seven timepoints during one session
12. LDL (mmol/L) is measured using blood tests at seven timepoints during one session
13. HDL (mmol/L) is measured using blood tests at seven timepoints during one session
14. Total cholesterol (mmol/L) is measured using blood tests at seven timepoints during one session
15. Triglycerides (mmol/L) is measured using blood tests at seven timepoints during one session

Key secondary outcome(s)

1. Ferritin (ng/ml) is measured using blood tests before each of the 2 test days
2. Glucose (mmol/L) is measured using blood tests before each of the 2 test days
3. Insulin (pmol/L) is measured using blood tests before each of the 2 test days

4. Bodyweight is measured using the Tanita TBF-300A Body Composition Analyzer scale before each of the 2 test days
5. Height is measured using a portable stadiometer (Charder HM200P Portstad Portable Stadiometer) at start-up
6. BMI is calculated as body weight (in kg) divided by the height in meters squared before each of the 2 test days
7. Blood pressure is measured using an A&D medical automatic blood pressure monitor (A&D, Tokyo, Japan) before each of the 2 test days
8. Pulse is measured using an A&D medical automatic blood pressure monitor (A&D, Tokyo, Japan) before each of the 2 test days
9. Total protein (g/100 g product) is measured using food product information
10. Amino acid composition (g/100 g product) is measured using food product information
11. Total fat (g/100 g product) is measured using food product information
12. Fatty acid composition (g/100 g product) is measured using food product information

Completion date

30/06/2025

Eligibility

Key inclusion criteria

1. Use of any medication except birth control pills
2. Not consuming meat and/or dairy products
3. No immediate desires to lose body weight (relevant for the Ad Libitum buffet test)
4. Food allergies
5. Problems with blood withdrawal or low blood pressure

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

40 years

Sex

All

Total final enrolment

25

Key exclusion criteria

1. Use of any medication except birth control pills
2. Not consuming meat and/or dairy products
3. No immediate desires to lose body weight (relevant for the Ad Libitum buffet test)
4. Food allergies
5. Problems with blood withdrawal or low blood pressure

Date of first enrolment

01/09/2021

Date of final enrolment

02/11/2021

Locations

Countries of recruitment

Norway

Study participating centre

Norwegian University of Life Sciences

Universitetstunet 3

Ås

Norway

1433

Sponsor information

Organisation

Norwegian Agriculture Agency

ROR

<https://ror.org/03ht51987>

Funder(s)

Funder type

Government

Funder Name

Landbruks- og matdepartementet

Alternative Name(s)

Ministry of Agriculture and Food, LMD

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Norway

Results and Publications

Individual participant data (IPD) sharing plan

The raw data as will be stored in the archive set for highest security by Norwegian University of Life Sciences defined by W: Lipidinflammagenes. Raw data are transferred to <https://nva.sikt.no/projects?id=https%3A%2F%2Fapi.nva.unit.no%2Fcrisin%2Fproject%2F2492957>

Once the paper is published the raw data are accessible to everyone upon request. The data will be anonymized, and the information form (invitation form) specifies that the data will be used for publication.

The internal sharing always uses coded and the identification list can only be accessed by project leader in the transition period to ultimate storage at nva.sikt.no

IPD sharing plan summary

Stored in publicly available repository, Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/05/2025	30/06/2025	Yes	No
Participant information sheet			28/10/2024	No	Yes
Protocol file			28/10/2024	No	No
Statistical Analysis Plan			28/10/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes