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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

Registration date
28/10/2024

Overall study status
Completed

Last Edited
30/06/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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 Egelandsdal (bjorg.egelandsdal@nmbu.no).

Study website
https://gammel.nmbu.no/en/projects/node/34902 This website is available until 31.06.2025 The long term webpage will be: https://nva.sikt.no/projects?id=https%3A%2F%2Fapi.nva.unit.no%2Fcristin%2Fproject%2F2492957

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Laboratory

Study type(s)
Quality of life

Participant information sheet
See outputs table

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 measure
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

Secondary outcome measures
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

Overall study start date
26/09/2020

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
26

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
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Sponsor information

Organisation
Norwegian Agriculture Agency

Sponsor details
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Sponsor type
Government

Website
https://www.landbruksdirektoratet.no

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

Publication and dissemination plan
The researchers plan to write one publication in a peer-reviewed journal

Intention to publish date
30/06/2025

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%2Fcristin%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?
Participant information sheet			28/10/2024	No	Yes
Protocol file			28/10/2024	No	No
Statistical Analysis Plan			28/10/2024	No	No
Results article		04/05/2025	30/06/2025	Yes	No