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Effects of meat and dairy fat on human health

Submission date
26/01/2022

Recruitment status
No longer recruiting

Registration date
22/03/2022

Overall study status
Completed

Last Edited
07/08/2023

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
The dietary intake of saturated fatty acids (SFAs) from dairy and meat products has been associated with negative health effects, especially on the cardiovascular system (heart and blood vessels). Meat and dairy products contribute 62% of the total SFA intake from the average Norwegian diet. There is a lack of causal evidence between SFA and heart disease. In addition, it is unknown whether sources of SFA, such as dairy, pork and cattle, could affect heart disease risk differently. The aim of this study is to investigate whether different animal products (two types of cheese, beef and pork meat) affect health parameters in healthy young individuals.

Who can participate?
Men and women aged between 18 and 40 years, body mass index (BMI) between 18.5 and 30 kg /m², healthy, and with less than 10 hours of physical activity per week

What does the study involve?
Participants consume four different diets in a random order, each lasting 2 weeks followed by a 2-week break. The total duration of the study is 4 months. All participants receive a varied healthy diet plus one of the test products (150 g of cheese or 225 g of pork or 230 g of beef, respectively) for 2 weeks. During this period, the participants should only eat the food items provided. The diets are provided by the researchers and include a healthy diet (rich in fruits, vegetables and fiber) plus one of the four sources of animal fat: gouda cheese, Swiss cheese, beef or pork. Before and after each intervention period fasting blood, faeces and urine samples are collected (eight times in total). In addition, at the start and during the three break periods, all participants record everything they eat for 3 days.

Where is the study run from?
Norwegian University of Life Sciences (NMBU) (Norway)

When is the study starting and how long is it expected to run for?
July 2018 to October 2022

Who is funding the study?
The Norwegian Agriculture Agency (Norway)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
281297

Study information

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

Acronym
LIG-IN-one

Study objectives
To investigate how different animal fat sources (from cheese, beef and pork) affect human health.

Ethics approval required
Old ethics approval format

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

Study design
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, beef or pork meat

Interventions
The study has a crossover design with four different diets. The randomization is carried out according to a Latin square design in order to assure that all test diets are equally distributed. Each of the four diets is carried out for 2 weeks followed by 2 weeks of washout in a crossover design. The test diets are provided by the researchers and include a healthy diet (rich in fruits, vegetables and fiber) plus one of the four sources of animal fat: gouda-type cheese (150 g), Swiss-type cheese (150 g), beef (230 g) and pork meat (225 g), to be eaten in two or three meals.

Intervention Type
Behavioural

Primary outcome(s)
Blood values measured eight times; before and after the four test diet periods of 14 days:
1. Total serum triacylglycerol (before and after 14 days of each intervention) (mmol/l)
2. HDL-cholesterol (before and after 14 days of each intervention) (mmol/l)
3. LDL-cholesterol (before and after 14 days of each intervention) (mmol/l)
Serum lipids are measured using accredited methods at a commercial medical laboratory in Norway. The changes in the lipid profile before and after the dietary interventions will be the primary outcome (mmol/l)
4. Inflammatory markers (interleukin-1 beta and interleukin-6) measured by enzyme-linked immunosorbent assay (ELISA) using fasting serum samples before and after 14 days of each intervention (pg/ml)

Key secondary outcome(s))
Measured at fasting using accredited methods at a commercial medical laboratory in Norway using serum samples taken before and after the four test diet periods of 14 days:
1. ALT
2. AST
3. Insulin
4. C-reactive protein
5. Blood glucose
6. C-peptide pmol/L serum
7. 25-OH D3 nmol/L serum
8. Apolipoprotein A
9. Apolipoprotein B
10. Calcium
11. Ferritin
12. Iron
13. Vitamin B12

14. Lipid species (metabolites) measured by chromatography coupled to mass spectrometry-based metabolomics using serum samples. Calculated as fold changes in relation to pre-intervention values
15. Diet registration: collected four times at baseline and during the three washout periods (3 days in each period, totalling 12 days of diet registration). Complete registration of what the participants ate (4 x 3 days are requested). Computer tool used: Norwegian Directorate of Health

/Norwegian Food Safety Authority. (2021). A diet tool from the Norwegian Directorate of Health and the Norwegian Food Safety Authority. Kostholdsplanleggeren (in Norwegian and English), available at: https://www.kostholdsplanleggeren.no/.

Measured before and after the four test diet periods of 14 days:
16. Bodyweight measured using the Tanita TBF-300A Body Composition Analyzer scale
17. Height measured using a portable stadiometer (Charder HM200P Portstad Portable Stadiometer)
18. BMI calculated as body weight (in kg) divided by the height in meters squared
19. Blood pressure measured using an A&D medical automatic blood pressure monitor (A&D, Tokyo, Japan)
20. Pulse measured using an A&D medical automatic blood pressure monitor (A&D, Tokyo, Japan)
21. Microbiota measurements of feces using 16S rRNA sequencing with Illumina

Completion date
01/10/2022

Eligibility

Key inclusion criteria
1. Men and women
2. Age between 18 and 40 years
3. BMI between 18.5 and 30 kg/m²
4. Healthy
5. Less than 10 hours of physical activity per week

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
50

Key exclusion criteria
1. Use of any medication except birth control pills
2. Not consuming meat and/or dairy products

3. Willing to lose body weight
4. Food allergies
5. Problems with blood withdrawal or low blood pressure.

Date of first enrolment
01/10/2020

Date of final enrolment
28/02/2021

Locations

Countries of recruitment
Norway

Study participating centre
Norwegian University of Life Sciences
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Sponsor information

Organisation
Norwegian Agriculture Agency

ROR
https://ror.org/03ht51987

Funder(s)

Funder type
Government

Funder Name
Norwegian Agriculture Agency

Results and Publications

Individual participant data (IPD) sharing plan

The raw data as used in a scientific publication will be stored at https://archive.sigma2.no. To this file the researchers will add a DOI number that will link to the raw data. Provided acceptable to the journal the DOI number linking to the raw data will be sent to the accepting journal. 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.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Lipidomics results	03/03/2023	07/08/2023	Yes	No
Participant information sheet	Participant information sheet	23/01/2022	16/03/2022	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file		15/03/2022	16/03/2022	No	No
Statistical Analysis Plan			16/03/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes