ISRCTN25014465 https://doi.org/10.1186/ISRCTN25014465

Do feed-induced nutrient differences in cattle meat affect consumers' health?

Submission date	**Recruitment status**	[_] Prospectively registered
17/12/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
21/12/2021	Completed	[X] Results
Last Edited	**Condition category**	[X] Individual participant data
18/07/2022	Other	

Plain English summary of protocol

Background and study aims
Bovine meat (beef) is a valuable food source providing nutrients that are vital for good health. However, red meat has been given negative attention due to concerns for greenhouse gasses and links between red meat and risk for non-communicable chronic diseases. The aim of the study was to investigate the health effects of the optimized beef (from bulls fed with extra supplementation of selenium, vitamin D, E, K and omega-3 [Nutrient optimized, SeDK-feed]) compared to regular beef (from bulls fed with regular feed concentrate.

Who can participate?
Healthy, young, normal-weight females could participate.

What does the study involve?
A total of 34 free-living young healthy women consumed 300g of raw weight beef per day of one of the two beef types in a cross-over design. Diet registrations and fasting blood samples, anthropometric and clinical data were collected four times.

What are the possible benefits and risks of participating?
The possible benefit to the participants is that they learn how an intervention is carried out. The risk of participating is negligible beyond the discomfort possible with blood sampling.

Where is the study run from?
The Norwegian University of Life Sciences

When is the study starting and how long is it expected to run for?
September 2014 to April 2017

Who is funding the study?
The Norwegian Agriculture Agency Grant no 224794

Who is the main contact?
Professor Anna Haug, anna.haug@nmbu.no

Contact information

Type(s)
Scientific

Contact name
Prof Anna Haug

ORCID ID
https://orcid.org/0000-0003-4704-699X

Contact details
Arboretveien 6
Faculty of Biosciences
Norwegian University of Life Sciences
Ås
Norway
1433
+47 99253637
anna.haug@nmbu.no

Type(s)
Scientific

Contact name
Prof Bjørg Egelandsdal

ORCID ID
https://orcid.org/0000-0003-0877-4628

Contact details
Postbox 5003 Christian Falsens vei 1
Ås
Norway
1433
+47 93847125
bjorg.egelandsdal@nmbu.no

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
The Norwegian Agriculture Agency Grant no 224794

Study information

Scientific Title

Identification of the healthiest beef meat for Norwegian women

Study objectives
1. Optimize beef meat for healthiness regarding nutrients
2. Study the healthiness of optimized beef meat in humans

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/01/2017, The Norwegian National Research Ethics Committee, Regional Committees for Medical and Health Research Ethics (Kongens gate 14, 0153 Oslo, Norway; + (47) 23 31 83 00; post@forskningsetikk.no), ref: 2016/620

Study design
Double blind randomized cross over clinical trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Changes in health parameters after ingestion of optimized beef meat

Interventions
The crossover clinical study is carried out for 32 days and contain two intervention periods, each lasts 6 days, with 14 days of washout. During each intervention period, the participants consume 300 g minced beef meat (as raw weight, regular or optimized beef) from forequarters, in combination with their chosen habitual food items, except fish in random order. The meat is from bulls fed regular control composite feed (REGULAR beef), and from bulls fed composite feed supplemented with vitamins D, E, K, omega-3 and selenium (SeDK-beef). The minced beef meat from the SeDK animals contain more selenium (+26%), vitamin MK4 (+123%), vitamin D (+197%), vitamin E (+318%) and has a lower omega-6/omega-3 ratio (-24%) compared to the REGULAR beef.

The participants are randomly split into 2 groups (2x17 persons) where one group is given the treatment (feed fortified cattle meat SeDK) and the other group is given a regular feed (REGULAR) mimicking commercial feed. The randomization is done in Excel using RANDARRAY. Blood sampling, blood pressure, heart rate, and selected anthropometric measurements are carried out before receiving the test product.

All participants are given the coded test product on the same start-up day. The coded meat product is handed out by persons who do not know what the code means. It is impossible to visually see the differences between test products, so each product just has a code. The participants start consuming the test product the very same day and 5 consecutive days (sum 6 test days). Then the participants return for blood sampling, blood pressure, heart rate, and selected anthropometric measurements before entering the wash-out period (14 days). Thereafter, the same procedure is repeated one more time. The order of arriving for the blood sampling etc is semi-randomized as adaptation to public transport and lectures are accepted.

The blood sampling is done in a Medical centre (Follo Bedriftshelsetjeneste, Ås, Norway), the participants are informed immediately regarding border values like low blood hemoglobin values while the intervention leader informs about border clinical values as soon as the analytical data are received from the analytical centre (Fürst medisinske senter, Oslo, Norway). The intervention leader has close communication regarding any questions the participants may have during the interventions and advise them regarding their diet registrations. Finally, the intervention leader invited the participants for a general meeting after the intervention about the general nutrient issues of young females.

Finally, each participant is formally interviewed 4 times during the intervention using a set of fixed questions/survey forms. As an example, they are asked about their perception of satiety related to their diet changes.

Intervention Type
Other

Primary outcome(s)
Blood values are measured 4 times; before and after the 2 test diet periods of 6 days)
1. Blood glucose mmol/L blood
2. Insulin pmol/L serum
3. C-peptide pmol/L serum
4. AST U/L serum
5. ALT U/L serum
6. AST/ALT
7. IL-1β ng/L plasma
8. IL-6 ng/L plasma
9. IL-8 ng/L plasma
10. HB g/100 ml blood
11. Triacylglycerol mmol/L serum
12. LDL-cholesterol mmol/L serum
13. HDL-cholesterol mmol/L serum
14. Selenium µg/L serum
15. Phylloquinone µg/L plasma
16. MK7 µg/L plasma
17. 25-OH D3 nmol/L serum
18. RNA deep sequencing of leucocytes isolated from fresh (10 min) plasma.

Key secondary outcome(s))
1. Test meat nutrient content (before the study starts) per 100g:
1.1. Selenium, µg
1.2. alpha-tocopherol, mg
1.3. K1, µg
1.4. MK4, µg
1.5. Vit D3, µg
1.6. 25-OH-D3, µg
1.7. Vitamin K
1.8. Cholesterol, mg
1.9. Fat, g
1.10. Fatty acid composition, mg

2. Diet registration (4 times; before and after the 2 test diet periods of 6 days)
3. 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 2 test diet periods of 6 days):
4. Bodyweight (kg)
5. BMI (kg/m²)
6. Blood pressure (mmHg)
7. Pulse (bpm)
8. Satiety by questionnaire

Completion date
15/04/2017

Eligibility

Key inclusion criteria
1. Women
2. Age (18-30 years)
3. BMI (18-28 kg/m²)
4. No medicine (except birth control pills)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
30 years

Sex
Female

Total final enrolment
35

Key exclusion criteria
1. Intake of medicine
2. Not perceive themselves as sick
3. Obesity

Date of first enrolment
10/01/2017

Date of final enrolment
15/01/2017

Locations

Countries of recruitment
Norway

Study participating centre
The Norwegian University of Life Sciences
Christian Falsens vei 1
Faculty of Chemistry, Biotechnology and Food Science
Ås
Norway
Postbox 5003/ 1433

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 will be submitted to the journal of choice.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/02/2022	18/07/2022	Yes	No
Dataset		08/02/2022	18/07/2022	No	No
Protocol file	in Norwegian	01/11/2021	21/12/2021	No	No
Protocol file	in English	22/03/2016	22/12/2021	No	No
Statistical Analysis Plan			21/12/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes