DO YOU WANT TO PARTICIPATE IN A RESEARCH PROJECT?

LipidinflammaGenes; an intervention project to study inflammatory markers and the risk of cardiovascular diseases, after ingestion of milk and meat products

THE PURPOSE OF THE PROJECT AND WHY YOU ARE ASKED

This is a question for you to participate in a research project to study the change in risk of cardiovascular diseases, inflammatory markers and satiety after ingestion of milk and meat products. Students at NMBU are hereby invited to participate in the study.

WHAT DOES THE PROJECT INVOLVE?

The study involves four 14-day periods during which you will eat foods that you are distributed and that contain different meat products or dairy products as test products. The diet is also put together so that it meets the requirements for micronutrients.

In between the three test diet periods, nothing happens, - you eat your regular food and you do not need to show up for any type of sampling.

The study will last a total of 14 weeks. In addition to blood tests, you need to collect morning urine and stool samples 8 times.

After each 14-day interventions, 1 hour for sampling is estimated, so the time spent on sampling will be about 8 hours in total.

You will be weighed, waist measurements will be taken as well as height, blood pressure and heart rate.

You cannot eat your usual food during the four 14-day interventions, nor can you drink more than five cups of coffee/tea per day and you must avoid alcohol and soft drinks during these four 14 days.

In the project, we will collect and record information about you. Blood sampling is used to investigate blood lipids, blood glucose, hemoglobin, cytokines, liver enzymes, and changes in RNA. You will also need to answer questions about satiety as well as about your usual dietary pattern.

Urine samples are taken to measure epigenetic and metabolic changes, feces samples are taken to obtain information about microbiota, energy absorbed and excreted, and which fatty acids are not absorbed.

POSSIBLE PROS AND CONS

Advantages are that you gain insight and knowledge about intervention studies in human nutrition research. In addition, you get free food for 4 x 14 days and a €50 gift card for a grocery store.

Disadvantage is taking blood samples and delivering urine and faeces samples. In addition, time usage is a disadvantage.

VOLUNTARY PARTICIPATION AND THE POSSIBILITY OF WITHDRAWING YOUR CONSENT

Participation in the project is voluntary. If you wish to participate, sign the declaration of consent on the last page. You may withdraw your consent at any time without giving any reason. It will have no negative consequences for you if you do not want to participate or later choose to withdraw. If you withdraw your consent, further research will not be carried out on your health information and biological material.

If you later wish to withdraw or have questions about the project, please contact the project manager (see contact information on the last page).

WHAT HAPPENS TO YOUR INFORMATION?

The information registered about you shall only be used as described under the purpose of the project, and is planned to be used until 2025. Any extensions of use and storage period may only take place after approval from REK and other relevant authorities. You have the right to access what information is registered about you and the right to have any errors in the data registered corrected. You also have the right to access the security measures taken when processing the data. You can complain about the processing of your data to the Norwegian Data Protection Authority and the institution's human data protection officer (No “personvernombud”).

All information will be processed without a name and national identity number or other directly recognizable information (=coded information). A code links you to your information through a list of names.

Only Catia Martins and Anna Haug have access to this list.

The information about you will be retained for five years after the end of the project for control purposes.

This project is a collaborative project between the Norwegian University of Science and Technology (NTNU) and the Norwegian University of Life Sciences (NMBU). The daily project leader for the intervention is from NMBU and the information is kept there.

SHARING INFORMATION AND TRANSFER OF DATA

By participating in the project, you also agree that coded information such as blood analysis and anthropometric data (blood pressure, heart rate, height, weight, waist circumference) may be transferred abroad as part of research collaboration and publication.

The code that links you to your personally identifiable information will not be disclosed.

WHAT HAPPENS TO YOUR BLOOD SAMPLES?

The samples taken by you must be stored in a research biobank ('LipidInflammagenes') associated with the project. Blood samples, urine and faeces samples are stored. Responsible Professor Catia Martins (NTNU, Department of Clinical and Molecular Medicine, Clinical Nutrition), but the samples will be stored at the University of Life Sciences, Faculty of Chemistry, Biotechnology and Food Science in the unit's room for

monitored freezers. Once the project's data has been analyzed, the remaining biological samples will be transferred to NTNU. If this is not of interest, the samples are destroyed and this is stated upon final notification of the project.

The biobank will be closed at the end of the project.

The sample material may be sent to be analyzed in Denmark or another European country, depending on the price quotes we receive on analyses. The sample material will then be destroyed after analysis has been performed.

Regardless of where the samples are sent abroad, they will not be traceable, as the code linking the samples to you will not be handed over.

GENETIC EXAMINATIONS

In the project, we will isolate ribonucleic acids (RNA) that play an important role in controlling the production of proteins. In this project, we will look at RNA that comes from circulating cells that play a role in the immune system. Based on such measurements, one can read which "defense" the body sets up at various foods. No feedback will be given to the participant.

1. Genetic guidance / random findings

   If abnormal findings are recorded, the project team will contact the participant about this. Participants will be contacted by e-mail and/or telephone. The project team can, if desired from the participant, assist and provide all relevant information about this to the participant's medical doctor (NO: fastelege).

- Possible re-identification
  It is informed that gene sequences are unique and can theoretically be returned to the owner.

INSURANCE

The Patient Injury Act that applies

ECONOMY

You will receive a €50 (NOK 500) gift card for use in a grocery store after the last sampling.

Free food is provided for 4 x 14 days

APPROVALS

The Regional Committee for Medical and Health Research Ethics has carried out a research ethics assessment and approved the project, case number 139404.

NTNU and project manager Catia Martins are responsible for the privacy of the project.

We process the data based on your consent.

CONTACT INFORMATION

If you have questions about the project or would like to withdraw from participation, please contact Catia Martins Catia.martins@ntnu.no, tel. 48603643, Anna Haug anna.haug@nmbu.no tel. 99253637, Bjørg Egelandsdal bjorg.egelandsdal@nmbu.no tel. 93847125

If you have questions about the privacy of the project, you can contact the data protection officer at the institution: NTNU's Data Protection Officer is Thomas Helgesen, thomas.helgesen@ntnu.no , +47 93079038 , Sluppenveien 12B/C, Møllenberg 4 etg, Trondheim

NMBU's human privacy policy is Hanne Pernille Gulbrandsen at Deloitte Law Firm, Mobile: 402 81 558, Email: personvernombud@nmbu.no

The Norwegian Data Protection Authority's e-mail address is https://www.datatilsynet.no/ post@datatilsynet.no

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I AGREE TO PARTICIPATE IN THE PROJECT AND TO THE USE OF MY PERSONAL DATA AND BIOLOGICAL MATERIAL AS DESCRIBED ABOVE

Location and date

Participant's signature

Participant's name with printed letters