



Participant information

Project title:

DD2 - Danish center for strategic research in type 2 diabetes

Approved by the Science Ethics Committee for the Region of Southern Denmark, journal no. S-20100082.

Looking for people with newly diagnosed type 2 diabetes for a national scientific project.

Project manager:

Professor **Henning Beck-Nielsen**.

Program leader and associate professor:

MSc. Ph.D. **Jens Steen Nielsen**.

DD2 - Danish center for strategic research in type 2 diabetes

OUH Odense University Hospital

Kløvervænget 6, 8th floor

5000 Odense C

Your local survey site is:



RESUME - of participant information for

The project: DD2 - Danish center for strategic research in type 2 diabetes

Before you decide, please read all of this participant information:

Who can participate

- People over the age of 18 with newly diagnosed type 2 diabetes (diagnosed within the last 2 years).

If you say YES to participate, you accept that

- undergo the DD2 examination, which takes about 30 minutes and implies that you should
 - Answer questions about lifestyle and diabetes in the family
 - Have measured hip and waist circumference, resting heart rate, height and weight.
 - Attend fasting for a blood sample, i.e. have not eaten food except water from 22.00 o'clock the night before. Also, do not take blood sugar control medication while you are fasting.
 - Hand in a morning urine sample.

In addition, you agree that

- DD2 anonymously stores and uses your data, including blood and urine samples for research into type 2 diabetes.
- The DD2 Center may contact you about new diabetes projects once the Scientific Ethics Committee has approved them. Participation is voluntary.
- DD2 sends you a questionnaire immediately after the DD2 survey and again after two, four and six years. It is voluntary if you want to answer.

Is there a risk involved in participating?

- There is no risk associated with participating.
- In very rare cases, the blood sample from the arm may briefly give a bruise or infection.

Your rights:

- It is voluntary to participate.
- Your data is treated confidentially.
- Participating in the project does not affect your current or future treatment.
- You can withdraw from the project at any time without justification.

What to expect of the project?

- The project is expected to provide new knowledge on how heredity, lifestyle factors and type 2 diabetes markers can be used in a more individually tailored treatment of type 2 diabetes.

Guide to the DD2 questionnaire on WebPatient

1. Log in to WebPatient via the link you receive in an email from your doctor's clinic

- Log in with your NemID.
- If you are using WebPatient for the first time, you must consent to the use of WebPatient. Then you move on to the DD2 form.

2. Give your consent to DD2

- Select "DD2" under "Mine aktive skemaer" when you are logged in
- On the DD2 form you can read the participant information or watch a video about DD2.
- Now give your consent to participate in DD2:
 1. Tick the box
 2. Confirm your approval on the button

Mine aktive skemaer	
Skemanavn	Oprettet d. ▼
DD2	22-03-2020

Ja, jeg bekræfter, at jeg godkender samtykke.

Bekræft godkendelse

3. Fill in the questionnaire

- Now answer the 8 questions related to your diabetes, which are shown to you.
- When in doubt, a question can be skipped and reviewed at the next appointment with your doctor or nurse.
- We recommend that the form is completed as correctly and adequately as possible.

4. Send the questionnaire to the doctor's clinic



Send your answers to your doctor's clinic by clicking on the button "Send til lægen" when you have finished filling out the form.

The button is on the left of the screen.

- Once you submit your answers, you will not be able to correct them. Also submit your form even if there are questions you cannot answer. If you want to correct an answer or have help with a question, this is possible when you arrive for your appointment at the doctor's clinic.
- You can subsequently log out. Remember your appointment at the doctor's clinic for blood tests.

PC or phone?

- We recommend that you fill out the form on a PC rather than on your phone.
- It is possible to fill out the form on the phone; the PC is more user friendly.



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Project title: DD2 - Danish center for strategic research in type 2 diabetes.

We would like to ask if you would like to participate in a national scientific project on type 2 diabetes, which is being carried out by DD2 - the Danish Center for Strategic Research in Type 2 Diabetes.

Before you decide, please read this information carefully. You are always welcome to ask questions.

Purpose and brief description of the project

The purpose of DD2 is to improve treatment for patients with type 2 diabetes and to follow the development of the disease in Denmark. This will be done through the Danish register system and by building up a national database with associated blood and urine samples; called a biobank.

The creation of the database and biobank also provides a unique opportunity to investigate whether the treatment can be adapted to a greater extent than hitherto to the individual patient with type 2 diabetes. Results will be published via articles in national and international journals, which can be found via www.dd2.dk.

It is DD2's wish that all persons over 18 years of age with newly diagnosed type 2 diabetes diagnosed within the last 2 years, participate in the project.

New scientific studies can be initiated. Your acceptance of participation also implies an acceptance that the DD2 Center may contact you regarding new studies in the future. However, you will under no circumstances be required to participate in such studies. In addition, future studies must be approved by the Science Ethics Committee for the Region of Southern Denmark before we can contact you.

Storage of data and biological material

All your data as well as blood and urine samples are marked with a code so that your identity cannot be revealed. A blurring of your identity ensures that you cannot be identified when data and samples are stored, analyzed and published.

Everyone who works with your data is subject to the legislation on professional confidentiality and the Danish Data Protection Agency's regulations regarding the handling of personal data.



The DD2 study

You must attend to give a blood sample and either undergo a short interview or answer an electronic questionnaire before.

For blood sampling, you must attend while fasting. Thus, you must not have eaten food other than water from 22.00 o'clock the night before. Also, do not take blood sugar control medication while you are fasting. The blood sample totals approximately 90 milliliters. Finally, bring a morning urine sample of approximately 10 milliliters.

During the interview or in the electronic questionnaire, you will have to answer questions about your general health conditions, your exercise habits and whether there is diabetes in the family. You will have your heart rate, height (if interviewed), weight and circumference of your hip and waist measured. We also ask if you have an email address, as we would like to send you an electronic questionnaire after the DD2 survey is completed and again after two, four and six years. It is optional if you want to give your e-mail and answer the subsequent questionnaires sent.

Analysis of biological material

Blood and urine samples are sent to a biobank, where they are frozen and stored for later analysis. No results are given back. Therefore, there are no immediate results that can be used in your treatment.

The blood samples will be analyzed for genetic variations and different type 2 diabetes markers. Some analyses are performed abroad.

The remaining blood and urine samples in the biobank can only be used if permission has been given in advance by the Science Ethics Committee for the Region of Southern Denmark and DD2's professional advisory forum. At the end of the DD2 project, all material in the biobank is destroyed.

Risk in the study

There is no risk in the DD2 study. However, while taking the blood sample, there is a minimal risk of infection, which may cause local itching or irritation of the skin for a few days. In addition, blood withdrawal can very rarely cause local bleeding, which may briefly leave a bruise.

Right of withdrawal

You can withdraw your consent at any time and without justification by contacting the DD2 Center. Should you no longer wish to participate, it will not have consequences for your current or future treatment.

Reimbursement

No compensation is paid in connection with participation in the project.



Usefulness of the experiment

New research shows that type 2 diabetes can be divided into several subgroups, which can be characterized by using genetic analysis, new biological type 2 diabetes markers, and study of lifestyle-related factors. With an improved characterization of type 2 diabetes, the treatment can be made more individually tailored than is the case today. This will lead to a reduction in the number and extent of type 2 diabetes-related comorbidities, thereby improving the individual patient's quality of life and well-being.

Information on financial matters and project participants

In the period 2018-2022, DD2 is financed by a grant from the Novo Nordisk Foundation (DKK 40 million) with Executive Vice President Kurt Espersen, Region of Southern Denmark as the grant recipient. A board and a professional advisory forum handle the overall management, while the daily management is done from the DD2 center located at Steno Diabetes Center Odense, Odense University Hospital (see organization at www.dd2.dk). DD2 is also directly and indirectly supported by the five regions.

Historically, DD2 has been supported by the Strategic Research Council (DKK 40 million), the National Board of Health (DKK 1 million), the Diabetes Association (DKK 0.5 million), Novo Nordisk (DKK 1 + 12 million), Region of Southern Denmark (DKK 1 + 1.6 million) and the Novo Nordisk Foundation (DKK 9.6 million). The historical partners can be seen at www.dd2.dk. None of the responsible applicants, partners or project managers are financially related to the contributors.

Partners in DD2 in the period 2018-2022

1. Aarhus University Hospital presented by **Data management**: Professor Henrik Toft Sørensen, MD, DMSc, Aarhus University Hospital.
2. Lillebælt Hospital, Vejle represented by **Biobanken**: Laboratory Manager Ivan Brandslund, MD, DMSc, Vejle Hospital.

Daily management

Chairman of the Professional Advisory Forum:

Professor **Henning Beck-Nielsen**, MD, DMSc, Odense University Hospital

Chairman of the Board:

Center Director at Steno Diabetes Center Odense **Jan Erik Henriksen**, MD, PhD, Odense University Hospital

Head of DD2 Center:

Lecturer **Jens Steen Nielsen**, MSc, PhD, Odense University Hospital.



Opportunity to appeal

You have access to documents in accordance with the provisions of the "Act on Public Access to the administration". If, as a result of your participation in the trial, an error or injury should occur to you as a patient, you should contact your doctor or the emergency room.

If you want to complain about the treatment in the DD2 project, you must send a complaint to the Danish Agency for Patient Complaints, see more at www.stpk.dk should the complaint provide a basis for compensation, it will be paid in accordance with Danish law. We ask you to read the leaflet "*Before you decide - to be a subject in health science research*" (www.nvk.dk).

You are always welcome to contact the DD2 center on telephone 65 41 36 25 and e-mail ouh.dd2@rsyd.dk.

Yours sincerely

Program leader and associate professor Jens Steen Nielsen

A handwritten signature in blue ink, appearing to be 'J.S.', written over a horizontal line.

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