Patient information for the ANDIS study ñAll New Diabetics in Scaniaò

Background and aim: Diabetes is a more heterogeneous disease than the current subdivision into type 1 (juvenile-onset) and type 2 (maturity-onset) would imply. Starting 2008, all patients with newly-diagnosed diabetes in the region of Scania will be asked whether they are willing to participate in the ANDIS study.
The aim of the ANDIS study is to try to classify your diabetes on the basis of blood sample taken and information in ANDIS registry. The overall vision is that a better classification of diabetes into subgroups will lead to a more individualized therapy.

Who will be asked to participate? You have been asked to participate in ANDIS because you have been diagnosed with diabetes during the last year and you live in the region of Scania.

How is the study conducted? In connection with a visit to your doctor or diabetes nurse your person ID number, name, address, time of diagnosis, initial and current therapy of diabetes, time of start of diabetes treatment, current height and weight, possible diabetes during pregnancy, information on diabetes in your family (father, mother, siblings, children etc) as well as information about in which country you and your parents were born. In addition, a blood sample is taken at the next visit which will help to classify your diabetes and a DNA sample for analysis of genetic factors of importance for diabetes. Also, one blood sample will be stored for possible future analysis. Your doctor/diabetes nurse will receive the results as soon as possible and within two months your doctor will receive a proposal for classification of your diabetes based upon the existing information.
The blood samples are stored in a biobank at the Clinical Research Centre (CRC) at SUS (responsible, Professor Leif Groop). The samples can only be used for the purpose you have given your consent to. The DNA sample will only be used to study genetic causes of diabetes, diabetic complications and other disorders related to diabetes.
If you previously have given your consent for registration in the National Diabetes Registry (NDR), we now ask whether this information annually can be linked to the ANDIS database. It is also possible to directly register information about your diabetes (treatment, diabetes control etc) in ANDIS.

Which are the risks? Except for the small discomfort of the blood sample the study does not bear any physical risks for you.

Are there advantages for you? A better classification of diabetes can hopefully lead to a more individualized treatment. However, this information will not be available until the end of the study. To the extent that knowledge already exists that could affect your treatment, the information will be conducted to your doctor.

Handling of data and data protection: In ANDIS the information about your diabetes will be stored in an electronic database or in a paper data base. If you agree to particicipate in the study you also consent to handling and storing of your data. All personal information as well as results from laboratory tests and other results will be stored and handled in a way that no one outside the project can get access to them.
Registration and sampling is voluntary. You can at any time withdraw from the study with no consequences for your future treatment and care. In accordance with the ñPerson Information Law ñ , Personuppgiftslagen (PuL) can you at any time ask to know which information about you is stored and also ask to correct incorrect information.

Responsible for storing of personal information is the Region of Scania. In the brochure ñ*How my personal information is handles in the Region of Scania***ò** *(Hur min personuppgifter behandlas I Region Skåne)* you will find general information on how personal information is handled in different operations in the Region.
The ANDIS study has been approved by the regional Ethics Committee in Lund. If we are planning new analyses we will submit a new application to the committee.

How can I get information about the results from the study? A summary of your laboratory results will be sent to your doctor. Information about progress of the project can be seen at the project website (http://andis.ludc.med.lu.se). In addition, the project group will organize annual information meetings for the caregivers.

Consent

1) I consent to taking the proposed blood samples and that they can be stored for classification of my diabetes.

Yes □ No □

2) I consent to storing my personal information and other information about my diabetes to be analyzed in accordance with the description in this Patient Information.

Yes □ No □

3) I consent that information about my diabetes annually can be obtained from the National Diabetes Registry (NDR).

Yes □ No □

4) I consent to be contacted for new studies related to ANDIS that concerns my diabetes and I can then choose if I wish to participate or not, without any further justification.

Yes □ No □

At registration

Place and date_____ Place and date_____

Signature_____ Signature_____

Name in print_____ Name in print_____

Person number_____

If you have questions about ANDIS please contact your doctor or

Leif Groop, Professor, Chief Physician
Lund University Diabetes Centre
UMAS, CRC, 20502 Malmö
Ph: 040-391202
Leif.Groop@med.lu.se

Ylva Wessman, Research Nurse
Department of Endocrinology
UMAS, 20502 Malmö
Ph: 040-333216/332331
Ylva.Wessman@skane.se