



Patient information for the ANDIU study

"All New Diabetic patients In Uppsala County"

1. Background and purpose:

Most probably Diabetes may be classified into more subgroups than currently is known. The objective of this study is to find means to classify Diabetes by a combination of patient history and DNA analysis. We believe that a more exact classification of Diabetes will facilitate optimal treatment and reduce the risk for suffering from complications.

ANDIU is solely financed by the Swedish Research Council as part of EXODIAB-Excellence in Diabetes Research and is designed and implemented by Uppsala University. ANDIU receive no commercial subsidiaries.

2. Who will be asked to participate?

You have been asked to participate in ANDIU since you live in Uppsala County and have been diagnosed with Diabetes during the past year.

3. What is the procedure of ANDIU?

- (I) You will be asked to fill in a questionnaire about your health, family history of Diabetes and your and your family's ethnic origin. The purpose is to find genetic markers that are still unknown and may help us to better understand Diabetes and improve treatment. In addition we will record weight, height, waist circumference, heart rate and blood pressure. This part of ANDIU will take about 10 minutes of your time.
- (II) A blood sample (about 20 ml) to analyse your ability to produce insulin, presence of antibodies and to screen for genetic factors associated with diabetes (DNA) will be taken. One test tube is saved for future analysis. Your doctor will receive the results as soon they are analysed. The test tube saved is kept frozen in a biobank at the clinical research unit CRC, Skåne University Hospital, Malmö in a way it is not directly related to your civic number. In charge of the biobank is Professor Leif Groop. Tis blood can only be used in accordance to the consent you have given.

Have you previously given permission to register your details in the National Diabetes Register (NDR), you will be asked if this information annually may be copied to ANDIU database.

All results (blood tests and the responses you provided in the questionnaire and those obtained from NDR) stored in coded form at the clinical research unit (CRC) in Skåne University, Malmö. The code key kept locked in a safety deposit box of the Section of Endocrinology and Diabetologi, Akademiska Hospital, Uppsala. Responsible for this database is Professor Per-Ola Carlsson.

4. What are the risks?

Beside the discomfort of the blood test, the study has no physical risks.

5. Are there any advantages?

By screening for ability to synthesise insulin and presence of antibodies the risk for misclassifying your diabetes is minimised. This ensures optimal treatment right from the start.

6. How is the obtained data secured from unauthorised people?

Your test results and other results are stored and processed in a manner so no unauthorised person can access them. All information is stored encoded in a database at the Clinical Research Unit (CRC) in Skåne University Hospital, Malmö. The deciphering key is kept locked up at the Section for Endocrinology and Diabetology, Akademiska sjukhuset, Uppsala.

Registration and testing is voluntary. You have your full right to refuse participation without prejudice to your future treatment. According to Personal Data Act (PUL), you are entitled to request to know what information is about you and to correct inaccurate information. Responsible for the Database is the County of Uppsala.

ANDIU approved by the research ethics committee at Uppsala University and the Data Inspectorate.

7. How do I get information about the study's results?

A summary of your test results sent to your own doctor. Information about the progress of the project will be posted on a website (<http://www.andiu.uu.se>).

Consent to participate in the ANDIU study

1) I agree that blood samples are collected and saved for the classification of my diabetes.

Yes No

2) I agree that personal data and other information about my diabetes is stored and processed as described in patient information.

Yes No

3) I agree that information about my diabetes disease annually may be obtained from the National Diabetes Register (NDR).

Yes No

4) I agree to be contacted for additional information or for any other studies on diabetes.

Yes No

Place and Date _____

Signature _____

Printed Name _____

Civic number: _____

If you have questions regarding ANDIU, don't hesitate to visit <http://andiu.uu.se> or contact:

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