

Patient information and invitation to participate in:

Studies of autoimmune polyendocrinopathy – candidiasis –ectodermal dystrophy (APECED) in Europe

A European consortium funded by EU's 6th framework program has been established to increase knowledge on APECED in particular, and autoimmune diseases in general.

Specifically, we aim to include patients with APECED in a European patient registry and biobank in order to describe the clinical manifestations of APECED in detail and to study the natural cause of the disease. . The new knowledge we hope to obtain will help as to understand, evaluate and treat APECED better than we do today, and help us understand other autoimmune diseases as well.

Blood samples will be used to investigate the immunological and genetic processes involved in the development of APECED. In particular, we will assay an array of autoantibodies (antibodies against self) and perform DNA-analysis of the autoimmune regulator gene, which is the disease-causing gene in this condition.

Participation in the study implies filling in a registration form together with your physician and giving a blood sample. We may also need to collect information from the patient records kept by your doctor or at hospitals where you have been treated. The collected information will be stored in a database in an unidentified state, which means that your name is substituted by a code. Your physician, not by the registry keeps the key to the code. The study will last for 3 years. Afterwards the information will be anonymised. All information we obtain will be treated with the outmost confidentiality, and no one outside the study group will have access to the information.

Participation in the study is voluntary and will not affect your treatment. Publication of the results will be done in such a way that individuals can not be identified. The physician responsible for your treatment will be informed about the results. The project has been approved by the local Ethics Committee and the Data Inspectorate of Norway. The Norwegian Social Science Data Services has been notified by the project.

Bergen, 1 October 2006,

On behalf of the EurAPS study group,

Eystein S. Husebye
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Norway

Written consent

I have received information about the project **Studies of autoimmune polyendocrinopathy – candidiasis –ectodermal dystrophy (APECED) in Europe** and agree to participate:

Patient:

Name: _____ Date of birth: _____

Address: _____

Patient signature: _____ Date: _____

Signature of parent/guardian (when applicable): _____ Date: _____

The patient has received written information and has agreed to participate

Physician:

Name: _____

Address: _____

Date: _____