

LETTER OF INFORMATION

Ref. Participation to the European study on familial IgA nephropathy

Dear Mr. and Mrs.

Your son/daughter suffers from IgA nephropathy or Berger's disease. We are involved in studying the genetic aspects of this disease by performing the analysis of urine and collecting the DNA from blood of patients and family members. This study is funded by the European Commission and approved by the local Ethical Committee. This research project is devoted to improve our knowledge in the pathogenesis of the disease and will not give immediate clinical benefits and will not improve the therapeutic management, of the disease.

Before asking you to participate, let me introduce some information on IgA Nephropathy which was described for the first time by professor Berger (Paris, France) more than 30 years ago. IgA nephropathy is a disease which presents blood in the urine coinciding with episodes of upper respiratory tract infection. Blood in the urine gives the characteristic red or coca-cola colour when present in large quantities (macrohematuria). In other cases the presence of blood in the urine is revealed microscopically by urinalysis (microhematuria). Hematuria may be associated with proteinuria and/or high blood pressure.

This disease is characterised by the deposition of the immunoglobulin A in the kidneys. Factors responsible for this deposition are unknown. The disease may involve one or more members of the family.

The aim of our study is to understand the genetic factors which may be responsible for the disease.

We need the analysis of your urine and a small sample of your blood which contains white cells. The DNA present in these cells will be stored in the genetic laboratory and will be used only for this study. In addition, a serum and plasma sample will be collected and used for biochemical and immunological parameter measurements. After the blood sample is taken you may have a small hematoma which disappears within 1 week.

If you do not wish to participate in the study we will continue to assist your son/daughter and your decision will not affect our support in any way. Please do not hesitate to contact us for further information.

All data obtained during the study will be enclosed in a database which will be encrypted preventing the access to third persons. In this manner the privacy of your family will be completely protected. This study will not provide immediate clinical benefits for patients and relatives, however if gene(s) will be identified at the end of the study, if you are interested, we will inform your family physician on the final results. You can contact us for additional information.

Thank you very much for your kind collaboration.

Yours sincerely.

LETTER OF INFORMED CONSENT

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Doctor (surname)(name).....

(Hospital)

informed us that our son/daughter is affected by IgA nephropathy. He asked us to participate to the European study "Genetic aspects on IgA nephropathy". The European Commission has funded this study which has been approved by the local Ethical Committee. The physician underlined that we are free to participate or not.

We received all information on the disease and on the participation in the study. For this reason we accept to participate in the study by giving urine and blood samples, in the established conditions.

We have been informed that we do not have to pay for this genetic research.

We know that this study will not benefit single participants nor will it improve the clinical course of the disease nor the therapeutic management.

We accept that our nameswill be included in the database of the European IgA nephropathy registry which will be encrypted for the protection of our privacy in according to the national law.

We know that all medical information will be given to our family physician (Dr..... Tel.....).

After discussing the aspects of the study and receiving all information requested, we accept to participate in the study.

We know that we can withdraw our participation at any time without damaging our relationship with Dr.

Date.....

Father.....

Mother.....

Signature.....

Signature.....

Medical investigator.....