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The National Study of Steroid Resistant Nephrotic Syndrome in Childhood

GP/Consultant Information Sheet

Purpose

The aim of this study is to further our knowledge of SRNS/FSGS (Steroid Resistant Nephrotic Syndrome/Focal Segmental GlomeruloSclerosis) in childhood in the UK population. This study has been set up in conjunction with RaDaR (the National Rare Kidney Disease Registry) and will utilise the cohort of patients in the UK that is being developed.

Background

SRNS/FSGS affects approximately 180 children in the UK currently and accounts for 10% of children on the end stage renal failure programme and approx 10% of children undergoing transplantation each year. With an estimated recurrence rate post transplant of 30% after the first and up to 100% following subsequent transplants this is a condition which causes a significant amount of morbidity.

Patient Identification

The patients will be identified by the Rare Kidney Disease Registry (RaDaR) to which they will have previously consented.

Details of the study

The study protocol describes the scientific background in detail but essentially this project will look at two components.

Firstly, the incidence of gene mutations causing SRNS/FSGS in children in an unselected population is around 20%. This project will perform mutational analysis for the genes that are known to cause FSGS in childhood namely Nephrin, Podocin, TRPC6, WT1, PLCe1, CD2AP and also α-actinin 4 which has not been tested in this age group.

This information will be analysed with clinical details obtained from the RaDaR database and comparative genotype/phenotype analysis will be performed. Also, we will perform analysis of outcome according to clinical entry parameters.

Secondly, in order to further understand the pathogenesis of disease recurrence post transplantation, blood and urine samples will be obtained from patients immediately prior to transplantation and within one week post operatively. Also, should a patient suffer disease recurrence post transplant and undergo plasma exchange, then plasma samples will be obtained.

These samples will be analysed for biological markers of disease activity. This will be performed using cell lines of conditionally immortalised podocyte cells.

To what is the patient consenting

The patient has already consented to their clinical information being uploaded onto the RaDaR database. Their clinical information will be utilised in a link-anonymised form from RaDaR and analysis will be undertaken by the research group and RaDaR.

For this study they will consent to a blood sample being taken with the next routine blood test which will be for the purpose of gene analysis.

Furthermore, should they undergo transplantation through the time period of this study, they will consent to blood and urine samples being taken during routine sampling immediately pre op and within 7 days post operatively.

Should they have disease recurrence post transplantation and undergo plasma exchange, plasma samples will be taken.

Length of Study

The study is planned for a period of five years in the first instance.

What happens to the samples at the end of the study?

The samples will be held in the Academic Renal Unit at the University of Bristol and preserved in -80degree freezers. At the end of the study time period they will continue to be held by the laboratory pending further study.

What if the patient wishes to withdraw?

A patient may withdraw at any stage. They will be asked to do this in writing to their local renal specialist or to the disease group directly. Any analysis already performed of samples previously collected will be used but no further analysis will be performed on those samples and no further sample collection will be performed. Any samples held by the research team will be disposed of appropriately.

Responsibility and Governance

The data is held securely by the RaDaR database which has separate ethical approval. The information is held in a disease specific web server and is encrypted at transmission. The information that the research group can access will be in a link-anonymised form (i.e. using a RaDaR identifying number only). RaDaR comes under the governance of the UK Renal Registry and Renal Association and will report back to their respective management boards.

The samples will be held in the Academic Renal Unit at the Southmead Hospital Campus of the University of Bristol in a locked facility. Access will be to the research group only and will require an ID swipe card.

Ethical Approval

This study has been approved by the North Somerset and South Bristol Research Ethics Committee (09/H0106/80).

Sponsorship

This study is sponsored by the University of Bristol.

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