PARTICIPANT INFORMATION SHEET FOR PARTICIPANT OR LEGALLY ACCEPTED REPRESENTATIVE

Title of the project: "Infectious and genetic triggers in children with hemolytic uremic syndrome"

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Aims and Purpose of Study

Your child has Hemolytic Uremic Syndrome (HUS), a condition that results in acute renal failure. These children are at high risk of progression to chronic renal failure. Treatment options available include the use of plasma-exchanges, supportive care including, as required, dialysis, and in some conditions, the use of immunosuppressive medications. Conventionally, most cases of HUS have been linked to a diarrheal or dysenteric illness. In many cases, HUS is not preceded by a diarrheal illness and the etiology is not identified. Some children with this disease have antibodies to a complement regulatory protein namely, complement factor H which regulates the complement pathway. In the rest of the cases, underlying genetic abnormalities in complement system can be responsible for occurrence of disease. Recognition of the underlying abnormalities can guide further management of the condition affecting your child. It is thought that an unknown infection might cause HUS in patients who are genetically predisposed. Overall, there is very little information on the underlying genetic abnormalities due to lack of diagnostic facilities. Also, there is no information on infectious causes that cause the disease.

Specialists dealing with children with HUS face many unanswered questions concerning the evaluation for underlying abnormalities and the optimal modalities for its management so as to prevent serious consequences and recurrence of disease. Some of these include: (i) What is the underlying abnormality that caused the disease in your child? (ii) Can the defect be corrected by some specific therapy? (iii) What outcome is expected? (iv) Is this condition likely to recur?

Information on these is difficult to collect since we do not have information on the specific infectious/ environmental cause of the disease and underlying inherited defects. To understand the underlying abnormalities, we are making an effort to examine infectious causes and genetic defects in samples collected from children with HUS, such as your child.

Procedure

Your child, who has hemolytic uremic syndrome, is invited to join the study in which nearly 50 patients shall be included. With your approval, your physician will collect basic information related to your child's condition such as age, complaints, findings on examination, laboratory values and therapies. For examination of infectious etiology, a blood sample of 2 ml (half tea spoonful), nasopharyngeal, throat swab and stool will be collected. For genetic testing for complement abnormalities, a blood sample of 5-7 ml (one and a half teaspoons) shall be obtained from your child once and its genetic material (DNA) extracted and stored. The sample will be given a unique ID to maintain confidentiality. Investigations shall be done to confirm the diagnosis and for presence of anti-factor H antibodies.

Expected duration of the subject participation

For purpose of this study, your child is expected to participate in the study once at the time of diagnosis of the disease. During and after this period your child shall be followed up through the outpatient clinic as are other children with this condition.

Risks from the study
No untoward risk to the patient is expected through participation in the study. The study involves observation of disease course and outcomes and does not involve any specific or new intervention. Standard protocols based on current guidelines for management of the disease condition shall be adhered to.

Benefits from the study
You and your child will not have any direct or indirect disadvantages in case you do not agree to participate. You may withdraw your consent at any time. Patients consenting to participate in the study of underlying defects in the complement pathway shall be tested for these abnormalities. Levels of autoantibodies in affected patients may be useful in guiding the intensity of their management in the form of plasma exchange and the use of immunosuppressive medications. Importantly, such testing for autoantibodies and other complement defects currently is not available elsewhere in the country.

Provision of free treatment for research related injury and compensation for disability or death resulting from such injury
For any complications arising from the primary illness, the child shall receive standard treatment at the AIIMS. AIIMS does not have any financial liability towards providing free treatment for nephrotic syndrome or any attendant complications, during this study. Compensation for lost wages (for parents), or discomfort for hospital visits shall not be provided.

Maintenance of confidentiality of records
The medical records of the patient shall be kept confidential and accessed only by the treating physician or, if necessary, by the Ethics Committee of the center at which your child is being managed. The entries of both clinical information and information on samples collected shall be anonymized in a coded manner as practised in international registries and biobanks so that the child and the family will not be identified by anybody accessing these databases.

Freedom of individual to participate and to withdraw from research at any time without penal or loss of benefits to which the subject would otherwise be entitled
You are free to participate in and with draw from this study at any time you so desire. This will in no way affect the ongoing treatment of your child at the Institute.

Name and telephone members or individuals to be contacted in case of any questions
If at any time during the course of study, you have any question or concern related to the study, you may contact the following doctors:
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