

INFORMATION SHEET FOR YOUNGER CHILDREN

Study Title

Short course daily prednisolone therapy at the time of upper respiratory tract infection in children with relapsing steroid sensitive nephrotic syndrome; the PREDNOS 2 study

Invitation to take part in this research study

We would like to invite you to take part in our research study.

Why have I been asked to take part?

You have a kidney illness called nephrotic syndrome. We are asking your help to find out the best way to help children with nephrotic syndrome to stay well.

Why is this project being done?

We are trying to find out whether giving children prednisolone (a steroid) for six days every time they get a cold helps to prevent them from getting protein in their wee.

What will happen to me if I take part in the research?

When you get a cold we will ask your parents or guardian to give you extra tablets for six days. These might be steroid tablets, or they might be a harmless dummy medicine.

To make this as good a test as possible, no one will know whether you are having steroid tablets or the dummy medicine until the test is finished. Everyone will have the same number of tablets, but if you are having the dummy medicine, they won't have any steroids in them.

Whether or not you are given steroid tablets or dummy medicine will be decided by chance, rather like tossing a coin.

Your care will be the same whether you have steroid tablets or dummy medicine and we will be checking you closely. You will have a diary to write down the results of your urine tests with your parents. Each time you see your doctor he will record the information from your diary.

A blood sample will be collected from you. We will use magic cream or spray – whichever you prefer. If you do not want to have a blood sample collected for the

purposes of the study that is okay, you can still take part in the study without giving a blood sample.

We will ask your parents to complete four short questionnaires about your behaviour and quality of life at the beginning of the study and at 3, 6, 9 and 12 months. This will take less than 20 minutes each time.

You will come back to see the study doctor every 3 months to check how you are getting on.

Will joining help me?

We cannot promise that the study will help you but the information we get might help treat young people with nephrotic syndrome with better medicines in the future.

Do I have to take part?

You do not have to take part in this test. It is up to you. If you decide now or at any time that you do not wish to take part in this test, you will still get the best treatment available. If you take part, you can change your mind at any time without giving a reason.

What if I don't want to do the research anymore?

If at any time you don't want to do the research anymore, just tell your parents, doctor or nurse. They will not be cross with you. Your doctor will help you decide which medicine is best to use afterwards.

Did anyone else check the study is okay to do?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. This study has been checked by the North West – GM Central Research Ethics Committee.

If you agree to enter this test then you may be asked to sign a form to say that you agree along with your mum, or your dad, or your legal representative.

Thank you for reading this.

You will be given a copy of this information sheet and a signed consent form to keep if you decide to take part in the study.

