

## OLDER CHILD AND YOUNG PERSON INFORMATION SHEET

### 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. Before you decide if you want to join in we would like you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with your family, friends and your GP if you wish. Ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

### Part 1

#### What is the purpose of the study?

Over three quarters of children and young people with nephrotic syndrome will experience relapses (i.e. the nephrotic syndrome coming back after initial treatment). There is known to be a strong link between upper respiratory tract infection (URTI – the common cold) and relapse. The study is going to test whether taking a 6 day course of prednisolone treatment at the time of URTI can reduce relapses occurring in children and young people with nephrotic syndrome.

So as the study can be the best possible test to see whether taking prednisolone at the time of URTI can help to reduce relapse occurring, half the patients will receive active prednisolone tablets and half will receive dummy prednisolone tablets. Prednisolone can cause side effects, for example, a puffy face or changes in mood, and this study will also find out if taking prednisolone at the time of URTI leads to more side effects.

#### What is the medicine that is being tested?

Prednisolone is a steroid drug which suppresses the immune system. Prednisolone is the standard treatment for relapsing nephrotic syndrome.

#### Why have I been invited to take part?

You have had 2 or more relapses of your nephrotic syndrome in the last year. We would like to study whether giving you prednisolone for 6 days when you have an URTI could reduce relapses of your nephrotic syndrome from occurring. We are asking 360 children from hospitals in the United Kingdom to take part.

### **Do I have to take part?**

No, taking part in the research is entirely voluntary. It is up to you and your decision will not affect the standard of care you receive. If you do decide to take part, you will be given this information sheet to keep and be asked to sign an assent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive. If you do not take part or you withdraw from the study, you will receive your doctor's usual treatment for nephrotic syndrome.

### **What will happen to me if I take part?**

You will receive a supply of either active or dummy prednisolone tablets. You will take these tablets for 6 days each time you have an URTI in 1 year. The treatment which you receive will be picked by a computer which has no information about you, that is, by chance. You will have an equal chance of receiving the active or dummy prednisolone tablets. You will then be followed up every 3 months for 1 year to assess your progress.

The study is double blind. Neither you nor your doctor will know whether you are taking active or dummy prednisolone tablets (although, if your doctor needs to find out he/she can do so). This is to make the study the best possible test of whether taking prednisolone tablets at the time of URTI can reduce relapse.

During the course of the study a single 10ml (two teaspoon) blood sample will be collected from you. Where possible, we will collect this when you are having other routine blood tests. If you do not want to have a blood sample collected for the purposes of the study that is fine, you can still take part in the study without giving a blood sample. There is a lot of information to suggest that nephrotic syndrome could be a genetic problem and DNA from blood samples from all children in the study will be tested to try to find out more about this.

We will ask your parents to complete four short questionnaires about your behaviour and quality of life at the beginning of the study and then every 3 months for 1 year. This should take less than 20 minutes on each occasion. These questionnaires will only be identified by your unique study number and date of birth in the month/year format to maintain confidentiality.

The rest of your treatment will be usual treatment for relapsing nephrotic syndrome. You will be asked to test your urine for protein in the usual way to see if the nephrotic syndrome is coming back. You will record the results in your patient diary and bring it with you to regular check-ups with your doctor. In this diary we will also ask you to record whether you have been unwell in any way, and record any visits to hospital or your doctor, along with any medicines that you have taken. Study follow-up visits will be at baseline and months 3, 6, 9 and 12. See Table 1 below. Information from the patient diary that you complete will be recorded in your medical record and on the study assessment forms during the study follow-up visits.

Table 1

<b>Study Follow-up Visits</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Baseline/Months	Baseline	Month 3	Month 6	Month 9	Month 12
Regular checkups that are part of the usual treatment for nephrotic syndrome (including documentation of recent medical/drug history, any parental concerns, physical exam, height and weight, and blood pressure check)	Yes	Yes	Yes	Yes	Yes

Blood sample for study	Yes (can be at any time in 12 month study period)				
Four short questionnaires about your child's behaviour and quality of life for study.	Yes	Yes	Yes	Yes	Yes

### **What other medicines could I have instead?**

At present, the large majority of children are given no extra treatment when they develop an URTI. There is no agreed standard therapy, though it is hoped that if the results of this study show a benefit to giving a short course of prednisolone, then this will become standard therapy nationally.

### **What are the side effects of the medicine and might I have some if I take part in the study?**

Prednisolone treatment can cause side-effects, including a puffy face and body and mood changes. Other side effects include weight gain, skin problems, osteoporosis (thinning of the bones), sore throat or mouth and an increased risk of infection. We do not know if patients having prednisolone treatment at the time of upper respiratory tract infection will get a lot more side effects.

Patients taking prednisolone should avoid coming into contact with chicken pox, should not suddenly stop taking prednisolone and should carry a steroid card that explains they are taking prednisolone. Your mum or dad should contact your doctor straight away if you come into contact with chickenpox unless you have been told this is not necessary because you are immune to chickenpox.

Patients taking prednisolone might not be able to have some vaccines. Therefore during the course of the study all live vaccines should be avoided. Routine live vaccines such as MMR can be given once immunosuppressive therapy has been stopped. Your GP will be informed of this.

### **Is there anything else to be worried about if I take part?**

Patients who get the dummy prednisolone treatment at the time of upper respiratory tract infection might have a greater risk of a nephrotic syndrome relapse. Patients who get the active prednisolone treatment at the time of upper respiratory tract infection might have a greater risk of side effects.

### **What are the possible benefits of taking part?**

We believe that a 6 day course of prednisolone treatment at the time of an URTI may reduce relapses. This cannot be guaranteed but the information we get from the study may help us to improve the treatment of children with nephrotic syndrome in the future.

### **Contact details**

For queries about the study or for further information please contact:

Dr Martin Christian, Telephone 0115 924 9924 x63832, PREDNOS 2 Chief Investigator

<Insert Local PI Name>, Telephone <Insert Local PI Tel. No.>, PREDNOS 2 Principal Local Investigator

The PREDNOS 2 study co-ordinating centre is located at the Birmingham Clinical Trials Unit, Institute of Applied Health Research, Public Health Building, University of Birmingham, Edgbaston, Birmingham B15 2TT. Tel 0121 415 9131, Fax: 0121 415 9135, Web address: [www.birmingham.ac.uk/PREDNOS2](http://www.birmingham.ac.uk/PREDNOS2).

**Thank you for reading so far – if you are still interested, please go to Part 2**

## **Part 2**

### **What happens when the research study stops?**

When the research study stops the results of the study will be published and the information we get from the study may help us to improve the treatment of children with relapsing nephrotic syndrome in the future. We know that the standard prednisolone treatment works well so prednisolone treatment will still be used for nephrotic syndrome. If a 6 day course of prednisolone at the time of URTI does reduce relapse it might be used in future as standard care. When the research study stops and the study results have been published you can request to be told which arm of the study you were in.

### **What if new information about the research medicine comes along?**

Sometimes during the course of a research study, new information is found out about the research medicine. If this happens, your doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form. Your research doctor may also discontinue you from the study if your safety is compromised at any time.

### **What if there is problem or something goes wrong?**

If you are harmed due to someone's negligence, then you may have grounds for a legal action but may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms should be available to you. Taking part in this study would not affect your legal rights.

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The contact details for the PREDNOS 2 Chief Investigator are: Dr Martin Christian, Telephone 0115 924 9924 x63832. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Any complaint about the way you have been dealt with during this study or any possible harm you might suffer will be addressed.

### **Will anyone else know I'm doing this?**

If you decide to take part in the PREDNOS 2 study all information which is collected about you during the course of the research will be kept in confidence. This means we will only tell those who have a need or right to know. Information about your disease and progress will be sent by your doctors to the PREDNOS 2 study office at the University of Birmingham Clinical Trials Unit, on paper and electronically, where it will be securely stored. If you consent to taking part in this study, your GP and the other doctors involved in your care will be informed. With your permission, your relevant medical records may be inspected by

authorised individuals from the Birmingham Clinical Trials Unit or your hospital. They may also be looked at by the study team and regulatory authorities. The purpose of this is to check that the study is being carried out correctly. If you consent to taking part in this study a copy of the consent form will be faxed to the Birmingham Children's Hospital Pharmacy Department who will send the study medicine direct to your home. To be able to send the medicine to your home they will also be told your name and address and will need to know your parent's telephone number.

### **What will happen to the blood sample I give?**

The blood sample will, where possible, be collected at a time when you are having a routine blood test performed. (If you do not want to have a blood sample collected for the purposes of the study that is fine, you can still take part in the study without giving a blood sample). Following collection, the sample will be sent to the Institute of Child Health, London (Prof Detlef Bockenhauer's laboratory), where DNA will be isolated. Half will be used in experiments to see if there is a genetic cause for nephrotic syndrome (by Prof Detlef Bockenhauer and Prof Robert Kleta) and the other half will be used by Dr Ania Koziell at Kings College, London and Professor Moin Saleem at Bristol University in other experiments using different techniques to look at genetic changes in relapsing nephrotic syndrome. Following completion of this work, any remaining DNA samples will be retained in the laboratories of Prof Bockenhauer/Prof Kleta in London and/or Dr Koziell/Professor Saleem in London and Bristol for use in future research projects investigating genetic factors and disease mechanisms in relapsing steroid sensitive nephrotic syndrome which may arise as a result of this work. Any such studies on these samples would require Research Ethics Committee approval. Your DNA sample will be identified only by your study number and date of birth in the month/year format.

### **What will happen to the results of the research study?**

Once the study has finished the results from all patients who took part in the study will be published in a scientific journal. The publication will appear when all the patients have completed the study and the results have been analysed. Your doctor can provide you with a copy of this publication if you are interested. We will also publicise the results on the study's website. Only anonymous data will be published and your name will not appear in any report, presentation or publication.

### **What will happen if I do not want to carry on with the study?**

You can decide not to continue with study at any time but, if you do, we would still like to follow-up your progress and your data would remain on file and be included in the final study analysis unless you request that they should not be.

### **Who is organising and funding the research?**

The PREDNOS 2 study is being co-ordinated by the Birmingham Clinical Trials Unit at The University of Birmingham and is co-sponsored by the University of Birmingham and Manchester University NHS Foundation Trust. The study Chief Investigator is Dr Martin Christian at Nottingham Children's Hospital. The study is supported by the British Association for Paediatric Nephrology and the Clinical Research Network for Children. The study is being funded by National Institute for Health Research Health Technology Assessment Programme. The research has been reviewed and approved by all these organisations. Your doctor will not be paid for including you in this study.

### **Who has reviewed the study?**

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.

**Thank you for reading this – please ask any questions if you need to**

**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.**