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The National Study of Steroid Resistant Nephrotic Syndrome in Childhood

Information Sheet for Adolescents

You are being invited to take part in a project. Before you decide, it is important for you to understand why we want to do it and what it means for you.

Please take time to read this and chat about it with others if you want.

Your kidney doctor will explain if there is anything that is confusing or if you would like more information. Thank you for taking the time reading this.

The purpose of this study

Your kidney doctor has made a diagnosis of Steroid Resistant Nephrotic Syndrome (SRNS) or Focal Segmental Glomerulosclerosis (FSGS). This is a condition that affects the kidneys that makes you leak out protein in your urine.

It can be a nasty illness and is difficult for the doctors to treat. It often keeps coming back.

For this reason the kidney research group in Bristol, want to find out more about it. They want to know why some kids get it and others don't. They want to know if it is because of our genes – these are inside all our cells and tell the cells how to work.

Some children with SRNS/FSGS need a new kidney or transplant. Unfortunately after a transplant the illness can sometimes come back. We want to know why that would happen.

Why have I been chosen?

The research team, although based in Bristol, are approaching every child with steroid resistant nephrotic syndrome or FSGS, in the United Kingdom.

Do I have to take part?

It is up to you to decide whether you take part. You are still free to change your mind and withdraw at any time without giving a reason. If

you decide not to take part or to come out of the study this will not affect the treatment you receive.

What will happen if I agree to take part?

There are four parts to this study:

Firstly, next time you have a blood test, a little extra blood will be taken. The amount of blood to be taken is a teaspoon. This will be sent to Bristol and tested for the genes.

Secondly, the research group will look at your medical information on the RaDaR website you have previously been told about and consented to.

Thirdly, if in the future you need a transplant (only some will) the group would ask for a little extra blood and urine to be taken when you have normal blood and urine tests before the transplant and then afterwards.

Lastly, a few children who have had a transplant might get the illness back. If so, they are often treated with something called 'plasma exchange'. During this your plasma (part of the blood) is swapped for new plasma. Instead of throwing the old plasma away, which is what normally happens, it would be saved for testing.

The tests on the blood, urine and plasma would be to look to see whether they contain something which changes the kidney cells and causes the disease.

What will happen to any information about me?

This project will only look at information about you without your name, address or date of birth. Even the samples will be labeled only with a number.

What will happen to my samples?

All samples will be kept in the University of Bristol Academic Renal Unit. Only people in the research group with special passes can get in. The samples are kept in a freezer until they are used. If there is any left at the end it will be kept.

What if I want to withdraw from the study?

Any patient may withdraw from the study at any time by writing to their local kidney doctor asking just that. However we would ask that you discuss it with your parent/guardian or kidney doctor first before withdrawing as it is difficult to come back in once you have left. If you do want to withdraw then we would destroy any of your samples that we had and we wouldn't collect any more, but we would use the results from tests we had already done.

How will I know the results of the tests?

We will send the results of the gene tests to your kidney doctor (unless you don't want them to) and they will tell you the result.

The results of the other tests will be put together and your specialist will explain the results to you.

Will my GP know about this research?

Yes, if you want. Your specialist will send an information sheet about the study to your family doctor and inform him or her of any results from the study.

Can I have more time to decide?

Yes. There is no time limit. You can discuss this with anyone you choose. You may also have a copy of the full research proposal if you wish.

What if new genes are discovered that can cause SRNS/FSGS?

The research-group want to test for all the genes known to cause SRNS/FSGS but some more may be found later. The group would like to be able to test for new ones if they are found unless you don't want to.

What do I do if I have concerns about the study?

If you are worried you can chat to your kidney doctor in the first instance. You can also contact the PALS service of the hospital where you are being treated.

Has this research study been approved by an ethics committee?

Approval has been received from the North Somerset and South Bristol Research Ethics Committee, reference number 09/H0106/80.

Researchers

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