What is the study about?

Many children with cystic fibrosis have treatment with an antibiotic called tobramycin given straight into the blood stream (called intravenous or IV). This helps treat your lung infections, but it can sometimes cause kidney problems. Your kidneys are the part of your body that clean your blood and make urine. We think that giving a medicine called rosuvastatin at the same time as the antibiotic could help protect your kidneys from damage.

To help us find out whether this is true or not, we need to do a research study called a clinical trial in children getting IV tobramycin where half of the children taking part also get rosuvastatin, and the other half do not.

Why have I been chosen?

We are asking young people with CF to take part in this study.

What is Rosuvastatin?

Rosuvastatin is a medicine that is normally used to treat high cholesterol in adults and children.

What will happen to me if I take part?

You will be in the study for about 6 weeks and you will normally have 5 visits as part of the study. As much as possible we will do the study visits and blood tests at the same time as you would normally have them. However, the study will usually mean having 2 more blood tests and visits than normal, and we will take a little more blood each time.

On the day you are due to start treatment with IV tobramycin you will need to come to the hospital earlier than usual. We will ask you some questions about your medical history and a doctor from the CF team will examine you. We will also:

- measure your height and weight,
- measure your lung function,
- collect some blood tests
- collect a urine sample
- collect sputum (spit) sample

Once these have been done you will be told your **treatment group** for the study. There is an equal chance of you being in either group.

- one group will take a rosuvastatin tablet each day they are having IV tobramycin.
- the other group will just have their IV tobramycin as normal.

Every day during your course of IV tobramycin you will need to:

- collect a urine sample
- fill in a diary to tell us the times you did your sample and had your medicines

You will have 3 study visits during your course of IV tobramycin:

- **1 day after starting**
- **8 days after starting**
- **On the final day of IV tobramycin**

At each of these visits we will take some blood tests and collect sputum samples, and check if you are having any side effects. At the day 8 and final day visits we will measure your height, weight and lung function.

If you are having your treatment at home you will need to attend the hospital on the day you start treatment, and usually for the day 1, 8 and final day visits. You can collect your daily urine samples at home, keep them in the fridge, and bring them to your next planned visit. We will give you the sample pots you need.

4 weeks after finishing your IV tobramycin we will see you for a final visit where we will do the same tests as at your first visit.

Any leftover samples from cough swabs and fluid collected during bronchoscopy, done as part of routine clinical care, will be put aside for this trial.

What are all the tests for?

All urine and some blood samples will be transferred to the University of Liverpool for lab analysis. There they will test your urine samples for 'biomarkers' which tell us how your kidneys are working, and another test to see how the rosuvastatin affects your infection. We will test a number of things in your blood to tell us how your kidneys, liver and muscles are, how you're responding to treatment, and the amount of tobramycin and rosuvastatin in your blood. Sputum and cough samples and fluid collected during bronchoscopy will be used to assess the types of bacteria growing and their sensitivity to antibiotics.

It is important that we do not give rosuvastatin to anyone who is pregnant. We will therefore do a pregnancy test before starting treatment in all girls of childbearing potential. If you are sexually active during the study you must use a barrier method of contraception. Your doctor will discuss this in more detail with you.

Do I have to take part?

No. It is up to you to decide whether to take part. If you are all happy to take part you will be asked to sign a consent form. If you decide not to take part, it will not affect the care you receive in any way. If you change your mind you can stop taking part in the study at any time. If you recently participated in another trial please ensure

that you are able to complete all trial visits for the previous study as well as taking on what is required for this current study.

What are the possible risks and benefits of taking part?

Like any medicine, rosuvastatin can have side effects. Rarely, it can have serious effects on your liver or muscles. Your CF doctor will explain these, and other possible side effects, to you before you agree to the study. We will monitor you very closely for any side effects during the study. If you are concerned you may be having a side effect from the rosuvastatin, please contact your CF team immediately for advice.

If the study shows that rosuvastatin does protect your kidneys, then there may be a benefit to you, and the study may help children and young people in the future. However, you will not be able to continue using the rosuvastatin at the end of the study, even if you have benefitted from it.

What will happen to my information?

We will store your information in paper records and on a computer database. You will only be identified using a code, not your name. When we store and test your samples they will also be labelled with a code, so that the people testing them will not know that they came from you.

Who is organising and funding the research?

This research is funded by the J P Moulton charitable foundation, and the Medical Research Council, and is organised by the University of Liverpool.

Who has checked the study?

This study has been checked by a NHS Research Ethics Committee. The Committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given sufficient information on which to make an informed decision to take part or not.

More questions?

Thank you for reading this. Have a talk with your parents and decide if you want to take part. If you've got more questions you can ask the person who gave you this sheet.

If you have any concerns you can speak to the study team, or call [insert local PALS number] to speak to the hospital Patient Advice and Liaison Service (PALS).

For more information you can contact the study co-ordinator:
[INSERT DETAILS]

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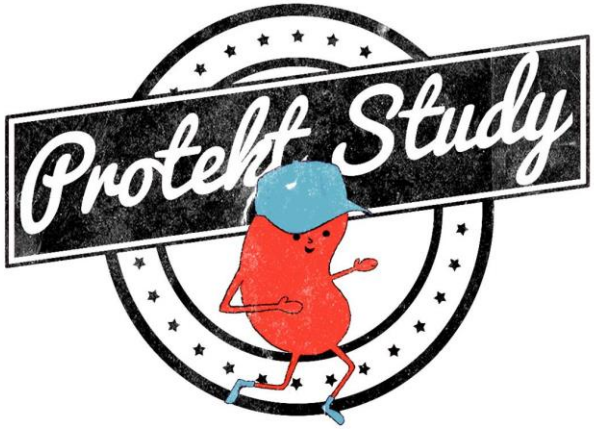
Alder Hey Children's NHS
NHS Foundation Trust



PROteKT
Information sheet for young people

Age 16 years and over