

What is the study about?

Many children with cystic fibrosis get an antibiotic called tobramycin given straight into the blood stream (called intravenous or IV). It helps treat your lung infections, but it can sometimes cause kidney problems. Your kidneys are the part of your body that 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.

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 (wee) sample
- collect a 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 time you did your sample, and what time you 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 come to 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 other procedures that your doctor thinks you need will also be collected for this trial.



What are all the tests for?

We 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. Your sputum sample will show us the type of bacteria present in your lungs.

Do I have to take part?

No. It is up to you and your parents to decide whether or not to take part. If you all decide to take part your parents will be asked to sign a consent form. We will ask you to sign a form called an assent form, but only sign it if you're happy to take part. Even if you say yes, but then change your mind, just tell someone, and you don't have to do it. No-one will be angry.

Will it affect me?

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?

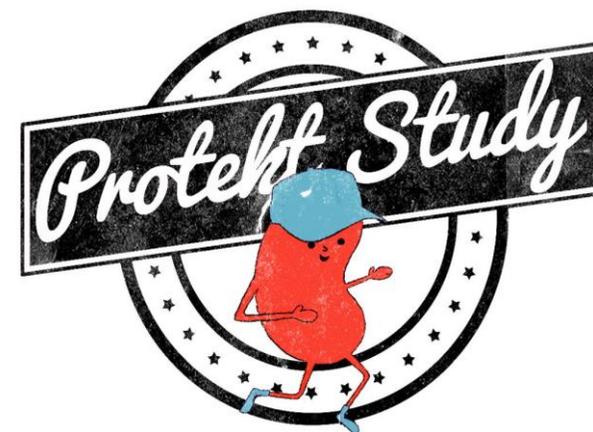
We will keep your information and samples safe and label them with a code, not your name, so people won't know they're yours.

Who is doing the research?

This research is organised by the University of Liverpool.

More questions?

Thank you for reading this. Have a talk with your parents and decide if you want to take part or not. If you've got more questions you can ask the person who gave you this sheet.



PROteKT Information sheet for young people

Age 10-12 years