



TORPEDO-CF: Trial of Optimal Therapy for Pseudomonas Eradication in Cystic Fibrosis

www.torpedo-cf.org.uk

We thank your mum or dad for helping you read this information

What is a study why is this study being done?



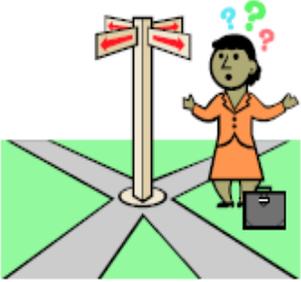
Research is what you do when you want to learn about something or find out something new.

This research looks at different medicines which are called antibiotics. They are used to help treat people with Cystic Fibrosis (CF) whose lungs have become infected with a germ or bacteria called Pseudomonas (pronounced sue-doe-moe-nas).

We know that both treatment types both work well at getting rid of the germ and preventing damage to the lungs, but we want to see if one works better than the other. So far there has not been any research carried out to test this.

There is a choice of treatment that can then be used to get rid of Pseudomonas– either antibiotics taken by mouth (orally) or given by a tube into the vein usually in the arm or the back of the hand (intravenous). Each is given with three months of inhaled antibiotic treatment through a machine called a nebuliser which allows you to inhale the medication as a mist directly into your lungs.

Children (6 to 10 years equivalent) Information and Assent Form
Please Note: the Parent / Guardian Information and Consent Form should also be completed.



Why have I been asked to take part?

You are being asked to take part in this study because you have CF and a lung infection caused by Pseudomonas that causes you to have health problems.

Do I have to take part?

No, not at all, it is completely up to you. Just say if you don't want to carry on. Nobody will mind.

If you agree to take part in the study, we will ask you to write your name on a form called an 'assent form'. This is to say you understand the study and what will happen. You will be given your own copy of this form to keep as well as this information sheet.

What will happen to me during the study?



The study will last for 24 months, during that time you will visit the study doctor at the clinic 9 times. Before you start, your doctor will tell you and your parents what will happen to you. Your doctor will ask you and your parents about when you have been ill in the past and what medicines you are taking.



During your treatment the doctor or nurse may take a little bit of blood from your arm and during the visits they will collect sputum (mucous you cough up from your lungs), ask you how you feel, and get you to blow into a machine to check your lungs. Your doctor will explain all of these.



What other treatment could I have instead?

The treatments used for this trial are usual antibiotics that would be used to treat lung infections of CF patients. If you decide not to participate in the study, then your doctor will discuss treatment options with you.

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Will taking the medicine upset me?

There is a small chance of having of an allergic reaction to the antibiotic, which could lead to an itchy rash. There is also a chance you might feel a little bit sick and have runny poo. Your CF team can talk to you about all the possible side effects.

What are the possible benefits or drawbacks of taking part?

Both treatments that will be used in the study have been shown to get rid of germs from the lungs of CF patients. However, this cannot be guaranteed. The information we get from this study may help us to improve future treatments for CF patients whose lungs have become infected with Pseudomonas.

Up to nine of your visits might take a little bit longer than normal because of the extra questions your doctor or nurse will ask you.



Will anyone else know I am doing this?

The doctors and nurses on the ward who are taking care of you will know. So will your doctor who usually looks after you, the study nurse and the study pharmacist.



How will the information about me be kept private?

Everything you tell us is private. The only time we would ever tell somebody what you have said is if something made us worried about you. All information collected for this study will be kept safely on a computer or as paper records. Of course, you can tell your family and friends about the study if you want.

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Who can I contact for further information?

Please feel free to ask your doctors any questions about the study or about any of the treatments.

What happens if a better medicine comes along?

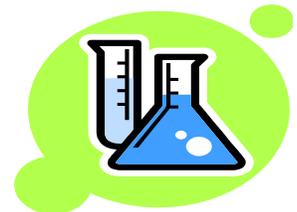
Sometimes during the course of a research project new things are found out about the research medicine. If this happens, your research doctor will tell you about it and will discuss with you whether you want to continue in the study.

What if there is a problem or something goes wrong?

If you have a question about any part of this study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain you can ask your parent or guardian how to do this.

What will happen to any samples I give?

As a part of the study, sputum and/or cough swab samples (mucous you cough up from your lungs) will be taken as part of your normal hospital care. These samples will be used to check for a range germs that may be in your lungs. If a Pseudomonas germ is isolated from your sputum or cough sample it will be collected and sent to an external laboratory for more tests to be done on the germ.



Thank you very much for taking time to read this. Please ask any questions if you need to.