Young persons (11-15 years equivalent) Information and Assent Form
Please Note: the Parent / Guardian Information and Consent Form should also be completed.

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

(www.torpedo-cf.org.uk)

Part 1 –to give you an idea about the project

We are inviting you to take part in a research study. Before you decide if you want to join it is important for you to understand why the research is being done and what it will mean for you. So please take time to read this leaflet carefully and discuss it with your family, friends, doctor or nurse if you want.

- **Part 1** tells you the purpose of the study and what will happen if you take part
- **Part 2** gives you more detailed information about how the study will be organized

Please ask your doctor if there is anything that is not clear or if you would like more information. You can ask the doctor or nurses whilst you are in hospital or if you would like to ask any questions after you have left hospital then there is a phone number and contact details on page 4. Thank you for reading this.

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1) Why are we doing this research?

Children and adults with Cystic Fibrosis (CF) are at risk of developing infection in their lungs which can cause health problems. A common cause of infection can be a bacteria or germ called Pseudomonas (pronounced sue-doe-moe-nas).

When Pseudomonas is first found in the lungs of CF patients they are treated with antibiotics (a type of medicine) to get rid of the germ. There is a choice of treatment that can then be used to get rid of the 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 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.

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

The only way to find out which of these treatments is better is to carry out a research project called a clinical trial where half the patients are given Treatment A and half given Treatment B. We hope the results of this study help us to treat other patients with CF in the best way possible in the future.

We have therefore designed a study to compare the two different antibiotic treatments. If you agree to take part you will be randomly given one of two groups.

What is the medicine that is being tested?

The medicines that we are testing are types of medicines called antibiotics. They help to stop the growth of, or get rid of, Pseudomonas in your lungs that can cause you to feel unwell.

Treatment A) Two antibiotics called ceftazidime and tobramycin will be given through a tube in your vein so the medicine goes straight into your blood. These medicines will be given to you over 14 days. At the same time, you will also be asked to take a medicine called colistin for 3 months by inhaling it into your lungs using a machine called a nebuliser.

Treatment B) You will be asked to take an antibiotic called ciprofloxacin by mouth (orally) as either a tablet or syrup for 3 months. At the same time you will also be asked to take a medicine called colistin by inhaling it into your lungs using a machine called a nebuliser.

2) Why was I asked to take part?

You are being asked to take part in this study because you have CF and we have identified lung infection cause by pseudomonas that causes you to have health problems.

This study will recruit 280 Adults and Children from CF centres throughout the UK.

3) Do I have to take part?

No, not at all! It is completely up to you if you want to take part or not! We only want people to take part if they want to so just tell us if you don't. Whatever you decide, you have the choice to stop taking part in the study at any time without giving a reason, nobody will mind, and it will not affect how you are looked after.

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.

4) What will happen to me during the study?

The study will last for 24 months, during that time your study doctor will collect information about your response to the study treatment and overall medical history. You will be asked to come into hospital for nine study visits. Study visits will take place every three months and should normally be scheduled to take place at the same time as your normal hospital visit.

Screening: If you are happy to take part, and are happy with answers to your questions, you will be asked to sign an assent form at the first clinic visit. You will be given a copy of the signed information sheet and consent / assent forms to keep. Once consent has been

taken you will be asked some questions about your medical history, and your study doctor will carry out a physical examination. This will take about 45 minutes.

Treatment: There is a 50/50 chance of you getting either Treatment A or Treatment B. No matter what treatment you receive, you will be followed up closely by your normal CF team.

Treatment A: treatment will be given through a tube in your vein (intravenous) over a period of 14 days, with each intravenous treatment lasting no more than 1 hour at a time. Three blood tests will be taken during the course of your treatment to monitor how well your kidneys are working and to check that you are getting the correct amount of tobramycin. These blood tests are carried out routinely as part of standard care for all patients receiving tobramycin. During this time, you will usually have to stay in hospital as an inpatient. It is sometimes possible to give some of this treatment at home and you could discuss this with your CF team.

Treatment B: treatment will be given as a tablet which you will need to take twice daily for 3 months.

**Both treatments will be given in conjunction with inhaled colistin for 3 months*

During your treatment you will asked to complete a daily treatment diary and to hand it in to your study doctor or nurse at the end of your treatment. The aim of this treatment diary is not to check that you have taken all your medication but will be used to keep an accurate record of when you have taken your medication.

You will also be given a short health diary to take home with you at each study visit and will be asked to return the diary when you attend hospital for your next study visit. This diary will allow you to record how many times you have seen your GP or other people involved in your care and will allow the study team to assess how the study treatment impacts on you.

Follow up: after you have stopped receiving treatment, you will be asked to attend hospital for a follow up visit every 3 months for 24 months after entering the study. During the visits you will have an examination performed by your study doctor, including a lung function test to measure if the treatment has improved your lung health. You will also be asked to provide sputum and / or cough samples (mucous you cough up from your lungs) which will allow your doctor to see if Pseudomonas in your lungs has been removed or come back.

As part of the study, you will be asked to complete some short questionnaires about how you are feeling. You will be asked to fill out these questionnaires before you start the study and at three, 15 & 24 months afterwards. The questionnaires will be completed when you attend for your treatment or follow-up appointments, and will take about 10 minutes to complete.

5) What other treatment could I have instead?

The treatments used for this trial are antibiotics that would usually 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.

6) Will taking the medicine upset me?

There are side effects to all types of medicines:

If you receive intravenous antibiotics there is a small risk of developing an allergic reaction to the antibiotic, in some rare cases tobramycin can cause kidney problems. However, if you are going to receive intravenous treatment you will be closely monitored by your CF doctor. You will have a blood test at the start of treatment to check your kidney function is normal and that you are getting the correct amount of antibiotic. You will also have two further blood tests taken during your treatment to carefully monitor the levels of antibiotic in your body. These blood tests are carried out routinely as part of standard care for patients that receive tobramycin. Tobramcyin can rarely affect your hearing.

Ciprofloxacin can make skin more sensitive to the sun and therefore more prone to sunburn; you should use sun screen when you know you will be in the sun. Other common side effects are feeling sick and development of diarrhea. Ciprofloxacin can rarely cause joint pain.

Your CF clinician will fully explain the possible side effects for both treatments with you before treatment begins. Should any side effects develop then you should stop taking the study medication and discuss further with your CF team who may feel that it is safe to continue or may wish to give you a different treatment.

7) What are the possible benefits or drawbacks of taking part?

Both treatments that will be used in the TORPEDO-CF trial have been shown to get rid of infections 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.

Both of these forms of treatment are available to you whether or not you take part in this study. The study will cause you a little added inconvenience because of the additional questions that you will be asked at a maximum of nine clinic visits.

8) Will anyone else know I am doing this?

Yes-

- The researchers who are running the study or research inspectors might want to see your medical notes to make sure the research is being done properly.
- Your family doctor will be told you are taking part.

If you agree to take part in the research, any of your medical records may be looked at to check that the study is being done properly. So that we can check that you agreed to join the study, a copy of the forms you and your parent/guardian wrote on to give your permission to take part in the study will be sent to the Medicines for Children Research Network Clinical Trials Unit (MCRN CTU) who are running the study and are based in Liverpool. The MCRN CTU will not tell anyone else your name and the form will be kept in a locked cupboard.

9) 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 described above.

THANK YOU FOR READING SO FAR- IF YOU ARE STILL INTERESTED, PLEASE GO TO PART 2:

Part 2: More detail – information you need to know if you still want to take part

10) What if new information about the research medicine comes along?

Sometimes during the course of a research project, new things are found out about the research medicine. Your doctor will tell you about it if this happens.

If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to stop taking part in the trial, the 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 assent form.

Also on receiving new information, your research doctor might consider it to be in your best interests to withdraw you from the study. Your doctors will explain the reasons and arrange for your care to continue.

11) 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.

12) What will happen to any samples I give?

As a part of the study, sputum and/or cough swab samples 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 germ called pseudomonas is isolated from your sputum or cough sample, it will be collected and sent to an external laboratory for more tests to be done. These samples will be used only for the TORPEDO-CF trial and for future Cystic Fibrosis related research and will not be used for any commercial purposes.

13) Who is organising and funding the Research?

The NHS Health Technology Assessment programme have provided the money to carry out this study. University Hospitals Bristol NHS Foundation Trust and the Medicines for Children Research Network Clinical Trials Unit (MCRN CTU), University of Liverpool are organising the study.

14) Who has reviewed the study?

Before any research goes ahead it has to be checked by an Ethics Committee. The Ethics Committee is a group of experts and ordinary people who look at all research studies very carefully. The committee decides whether the study is OK to do. Your project has been checked by the London Research Ethics Committee.

THANK YOU FOR READING THIS INFORMATION SHEET.
WE HOPE YOU HAVE FOUND THIS SHEET HELPFUL