



The use of induced sputum in monitoring infection in children with Cystic Fibrosis

STUDY INFORMATION SHEET FOR PARENTS

Dear Parents

Invitation

- Your child is being invited to take part in a research study. As the child's parent/legal guardian we are asking you to read this leaflet as you will be asked to make the decision on behalf of your child. We also have an information leaflet suitable for children should they wish to have one. Before you make a decision it is important to understand why this research is being carried out and what it will involve. Please take time to read this leaflet carefully and speak to others about it if you wish.

Background

What is the purpose of this study?

- In Cystic Fibrosis (CF), lung infection is common and needs to be treated aggressively with antibiotics even if it isn't causing many symptoms. Doctors need to use different antibiotics for different types of infection. In order to identify which bacteria is causing the infection, your child is often asked to give us a cough swab, so that a sample of your child's airway liquids can be sent to the lab to see if anything grows.
- Cough swabs are relatively easy to obtain but are not as good a test as bronchoscopy, where a fibre-optic camera is put down into the large airway of the lungs so that mucous samples can be taken directly from the lower airway. Obviously having a bronchoscopy is a much larger procedure than having a cough swab, but sometimes it is necessary. Some CF centres feel everyone with CF should have a bronchoscopy every year.
- The purpose of this research study relates to a third way of getting samples from the airway called "induced sputum". This is a little bit more complicated than a cough swab but much less complicated than having a bronchoscopy. It involves your child inhaling a fine mist of salt water and getting some physiotherapy. The salt water inhalation causes the phlegm (or sputum) to loosen up so that it can be more easily coughed up from the lower airway. We plan to compare the induced sputum to a cough swab and to a throat swab and to a nasal swab. If your child is going to have a bronchoscopy because your doctor feels he/she needs one, then we will compare these samples to the results of the bronchoscopy as well.

- In this research project we want to find out just how beneficial induced sputum really is, if we do it just once in the year, as part of the annual review, over and above the many cough swabs that are taken over the year anyway.
- Induced sputum can be done in the outpatient clinic or in the hospital ward and takes about 30 minutes. The technique is safe and used routinely in children with other respiratory illnesses. However, this kind of research needs to be done before we can start using the induced sputum technique routinely in patients with CF, as we need to be very sure that the procedure is well tolerated and also that it makes a worthwhile contribution to improving health care.

Why has my child been chosen?

- We are asking all children with CF over age 6 months who receive full care in Cardiff if they would like to be included in the study

Does my child have to take part?

- No. It is up to you and your child whether you decide to participate or not. If you do, you will be given this information sheet to keep and will be asked to sign a consent form on behalf of your child. You are still free to withdraw at any time and without giving a reason. A decision not to take part, or to withdraw at any time, will not affect the standard of care your child receives. Any samples or data files relating to your involvement in the study will then be destroyed immediately.

What will happen to my child if he/she decides to take part?

- One of the CF physiotherapists will take a cough swab and a throat swab and a nasal swab and then start the procedure for induced sputum.
- Oxygen saturation and heart rate will be monitored for the procedure. If your child is over 7 years then he/she will be asked to do lung function before the procedure starts.
- The procedure will involve a salty nebuliser (hypertonic saline) which will last about 15 minutes. After each 5 minute period, the physiotherapist will make an assessment of the chest and give appropriate physiotherapy or guide your child through breathing exercises to try and mobilise secretions. Any secretions will be collected either into a pot, or by suction from the back of the throat.
- Lung function will be taken again at the end of the procedure if appropriate.
- The final step is to take another cough swab.

What does my child have to do?

- Your child will be guided through the procedure as outlined above. The procedure will take place at about 12 o'clock and it is best if your child does not have anything to eat after 10am that morning

What are the other possible disadvantages and risks of taking part?

- All of the procedures being used in this study are already used by doctors in the treatment of children. Sometimes the salty nebuliser can make you cough and some children can wheeze. Generally it is well tolerated in all age groups.

What are the possible benefits to taking part in this trial?

- The main benefit of this research is for the CF community as a whole, as we explore whether induced sputum should become part of routine care. There are no immediate benefits to the

patient from taking part in this study, but should any organisms be identified from the samples taken, then appropriate treatment will be prescribed.

What happens when the research study stops?

- This research study is planned to run over five years.
- Once we have obtained a sample from your child, you and your child have made your contribution to the study.
- As the study lasts for three years it may be that you are approached again at subsequent annual reviews to go through the procedure again. There is no obligation for you to repeat the procedure just because you enrolled in the past. It would be entirely up to you if you wanted to contribute again.

If you are interested in taking part please read on for more details

What will happen if I don't want my child to carry on with the study?

- You are free to withdraw your child from the study at any time, including while he/she is performing the induced sputum test, and this will not affect the future care of your child.

Will my child taking part in the study be kept confidential?

- Yes. All information which is collected about you will be kept strictly confidential. Access to data which may identify you will be limited to the research team, who have a duty of confidentiality. Any information about you which is used outside the hospital/surgery will have your name and address removed and will only be identified by a code. Nothing which could reveal your identity will be disclosed outside the research site.

What will happen to the samples that my child provides?

- The samples will be sent to the labs to see what organisms can be identified. This will be done in the routine way, but also using a new state of the art approach using bacterial genetics, so that we can see if the new way works even better. These tests are not used routinely at the moment but may be in the future, and we need to see how well they work.
- These samples are very valuable to scientists as they are difficult to obtain. Here at the CF Unit in Cardiff we work with scientists who are very interested in inflammation in the lung and how the body responds to infection. We will collaborate with them in studies to look at inflammation.
- All samples will be supplied anonymously to researchers; only Dr Forton and members of his research group will be able to identify which samples your child donated. The recipients of the samples will not be supplied with your child's name or any other identifiable information and will not be able to identify your child from the samples.
- Any residual samples at the end of the study will be stored under a license from the Human Tissue Authority. License no: 12422.
- Your child's samples may be retained at the end of this study for use in future research within the UK and abroad. At this stage we do not know what the research will involve but some of it could include more bacterial genetic research and further research on lung inflammation. On the consent form you will be given the option to exclude your samples from these areas of research. Your child's samples will not be sold and will not be used in human genetic research, animal research or the commercial sector.
- **Current Use of samples in this study**
Participation in this study is voluntary and you are free to withdraw at any time without giving a reason and without your medical care or legal rights being affected.

If you do withdraw your consent your child's samples will not be used further in this study and will be destroyed according to locally approved practices. Any samples, or results derived from the samples, that have already been used prior to the withdrawal of consent will continue to be used in this study.

Future Use of samples in other related studies

You may withdraw your consent for the storage and future use of your child's samples at any point. If you do withdraw your consent, your child's samples will not be used in any subsequent studies and will be destroyed according to locally approved practices. Any samples already distributed for use in research prior to the withdrawal of consent will continue to be used in that study and any samples remaining at the end of the study will be destroyed.

What will happen to the results of this study?

- We intend to publish the study in a peer reviewed medical journal so that it can be seen by the rest of the scientific and medical community. The findings may also be presented at conferences. Such reporting is normal practice among researchers. You will not be personally identified in any report or publication.

Who is organising and funding the research?

- This study has been funded by a grant to Dr Julian Forton, consultant in Paediatric Respiratory Medicine, from the National Institute for Social Care and Health Research, Wales (NISCHR). It is being coordinated by Dr. Julian Forton here in Cardiff.

Who has reviewed the study?

- All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given a favourable opinion by the Wales REC2

What if there is a problem?

- If you have a concern about any aspect of this study, you should ask to speak to the researchers who can be contacted on the numbers listed below. They will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this [insert details eg NHS Complaints Procedure or Private Institutional arrangements]. Details can be obtained from [insert details]
- In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cardiff and Vale UHB but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.
- CONTACT DETAILS for researchers: 02920743530 or 0292074489

Thank you for taking time to read this leaflet. Please do not hesitate to ask a member of the research team if you would like to discuss anything further.



Dr Julian Forton
MA(Hons) MB BChir (Cantab) MRCPCH Ph.D

12th December 2014

If you have any concerns please do not hesitate to contact
Dr Julian Forton
Cystic Fibrosis/Respiratory Unit,
University Hospital of Wales,
Cardiff.
Tel 029 20743530 or 02920744891

Centre Number:

Study Number:

Patient Identification Number for this trial:

CONSENT FORM

The use of induced sputum in monitoring infection in children with Cystic Fibrosis.

Name of Patient:

Please initial box

1. I confirm that I have read and understand the information sheet dated 11/12/2014 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my child's participation is voluntary and that I am free to withdraw my child at any time, without giving any reason, without my child's medical care or legal rights being affected. ☐
3. I understand that relevant sections of any of my child's medical notes and data collected during the study, may be looked at by responsible individuals from the research team, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I understand that samples being collected in this research may be stored and used for future research. Any residual material will be stored under a license from the Human Tissue Authority. License no: 12422. ☐
5. I understand that I am able to withdraw my consent for this and /or other future studies study at any time. Any samples my child has donated which are still being stored will be destroyed at this stage ☐
6. I agree for my child to take part in the above study. ☐

Name of Parent

Date

Signature

Researcher

Date

Signature

Induced sputum in children with cystic fibrosis.
Project ID 11/RPM/5216.
Protocol Amendment version 2_11/12/2014
Julian Forton