Children's Hospital for Wales

GIG CYMRU NHS WALES

Bwrdd Iechyd Prifysgol Caerdydd a'r Fro

Cardiff and Vale University Health Board

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Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

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

STUDY INFORMATION SHEET FOR children aged >14 years

Invitation

- You are being invited to take part in a research study. As doctors, we are always doing research to find out how best to treat our patients. Without research we wouldn't know how best to treat you
- The research we are doing here in Cardiff is all about collecting samples of spit to grow bugs, and working out which is the best way to do this.

Background

Why are we doing a study?

- As you know we are always taking cough swabs from you. This is because doctors need to use different antibiotics for different types of infection.
- Cough swabs are quite easy to get but might not be the best way to get samples. Sometimes if we really need to know what's going on we do a bronchoscopy, where we put a tiny camera down the airway into the lung and collect samples of mucous from down in the lung. This is more of a big deal and so we don't do this very often. Some doctors think we should be doing this on everyone with CF every year to check what's going on.
- The purpose of this research study is to look at 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. What you have to do is inhale a fine mist of salt water and get some physiotherapy. The salt water inhalation causes the phlegm to loosen up so that you can cough it up more easily. That way we get a better sample. We plan to compare the induced sputum to a cough swab and to a throat swab and to a nasal swab. If you are going to have a bronchoscopy because your doctor feels you need 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.
- 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.

- Before we can start using the induced sputum technique routinely in patients with CF we need to be very sure that the procedure is well tolerated and also that it makes a worthwhile contribution to your care.

Why have I been chosen?

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

Do I have to take part?

- No. It is up to you and your parents whether you decide to take part. If you do, you will be given this information sheet to keep and you and your parents will be asked to sign a consent form. Even If you sign it you can pull out at any time.

What will happen to me if i 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.
- We will check your heart rate and oxygen saturations all through the study and you will be asked to do lung function before and afterwards.
- The procedure involves a salty nebuliser (hypertonic saline) which will last about 15 minutes. After each 5 minute period, the physiotherapist will make an assessment of the, give appropriate physiotherapy and guide you through breathing exercises to try and get secretions up.
- The final step is to take another cough swab.

What do I have to do?

- You will be guided through just what to do. The procedure will take place on the ward and it is best if you don't have anything to eat for two hours beforehand. The physiotherapist will time the procedure as it best fits in with you.

Are there any risks?

- 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 benefits to taking part in this trial?

- The main benefit of this research is for all the patients with CF as a whole, as we explore whether induced sputum should become part of your routine care.

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 have done your bit for 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. You don't have to do it again just because you did it this time. Its up to you.

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

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

- You are free to pull out of the study at any time, including while you are doing the induced sputum test.

Will people know that I'm taking part?

- All information which we collect about you will be kept strictly private. Only the research team will know about it, and you already know most of us.

What will happen to the samples that I give you?

- 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 you donated. The recipients of the samples will not be supplied with your name or any other identifiable information and will not be able to identify you 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 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 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 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 samples at any point. If you do withdraw your consent your 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 plan to publish the study when it is finished so that other doctors can use the information to help their patients. No-one will ever know that you were part of the study but they will know what the result was. We will send you an update as well.

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.

What if there is a problem ?

- If you have a concern about any aspect of this study, your parents 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. The contact details are: 02920743530 or 02920744891

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

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 2.0) 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 participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of any of my 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 I have donated which are still being stored will be destroyed at this stage ☐
6. I agree to take part in the above study. ☐

Name of Patient	**Date**	**Signature**
Researcher	**Date**	**Signature**