CF-HomeSpIT

The Cystic Fibrosis Home Sputum-induction Trial (CF-HomeSpIT) - self management for better microbiology surveillance

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Information leaflet for parents

Invitation to take part in a research trial

- Your child is being invited to take part in a research trial.
- As your child's parent/legal guardian please read this leaflet as you will be asked to make the decision along with or on behalf of your child.
- Before you decide, it is important to understand why this research is being carried out and what it will involve.
- We also have an information leaflet suitable for children

Background – The CF-SpIT trial

- The CF research team here in Cardiff have recently completed and published an important single-centre trial called *CF-SpIT* which showed that a simple procedure called sputum-induction is much better than cough swab at identifying bacteria in the lungs in children with Cystic Fibrosis. In fact, the trial showed that sputum induction was as good as bronchoscopy. The trial was published in the Lancet Respiratory Medicine journal in 2018 and has had a large impact across the world on how children with CF are managed.
- Now children with CF across the UK and the world are getting sputum-induction procedures in clinic. You and your child may have participated the *CF-SpIT* trial. 122 of the children we look after helped us in this trial. Thank you all very much!

What's the CF-HomeSpIT trial about?

- The trial we are planning now and which we are asking you and your child to participate in is called the Home sputum-induction Trial *(CF-HomeSpIT)* and this is looking at whether getting a sputum sample when you do physiotherapy at home before coming to clinic is as good as the sputum-induction procedure that we do in clinic.
- In this trial we will ask your child to try and collect 2 samples at home on the morning of a clinic visit: an early morning saliva sample taken first thing, and a sputum sample from when you do your child's hypertonic saline and physiotherapy that morning. We will then compare any bacteria that grow from these samples with samples taken on the same day in clinic (a routine cough swab, another saliva sample and another sputum-induction sample)

What is the purpose of this trial?

- Sputum induction is a little bit more complicated than a cough swab but much less complicated than having a bronchoscopy. It involves your child taking their hypertonic saline nebuliser, getting physiotherapy and then coughing up some mucous. This is usually performed by a physiotherapist in the hospital, either in clinic or on the ward.
- *CF-HomeSpIT* is important because our physiotherapists can't do a sputum-induction procedure on everyone in clinic because it takes time. Now that most people are on hypertonic saline at home, it

seems like a good idea to see whether older children who are able to cough up mucous, can do the procedure at home. This means our physiotherapists can concentrate on the younger children with CF who need specialist input to get sputum up.

Why has my child been chosen?

- We are asking all children with CF who use hypertonic saline as part of their home physiotherapy routine and who are able to cough up sputum to take part in the trial

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., and your child will be asked to sign assent to take part. 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 relating to your child's involvement in the trial will then be destroyed immediately, but samples analysed already will be used in the trial.

What would taking part involve?

- You have been sent this information pack in the post by your clinical team. One of the clinical or research team will contact you soon by phone to discuss the trial. If you are willing for your child to take part, they will be able to take informed consent from you over a system used within the hospital called 'Attend Anywhere'. You will then need to post your consent forms back to the research team in a pre-paid envelope.
- Closer to the time of your child's next clinic appointment in Cardiff (this may be their annual review), you will be sent a pack with all you need to perform the home sampling. You will receive another phone call to explain just what you need to do.
- You will then receive a final phone call on the day before your clinic appointment to remind you of what your child needs to do the next morning, and answer any questions you might have

- On the morning of clinic, we will ask you to collect 2 samples from your child. First, collect an early morning saliva sample first thing. Second do the normal physiotherapy session before breakfast, with the aim coughing up some mucous into the pot provided.
- When you come to clinic, you will need to give us your samples straight away so we can put them in the fridge. Your child will have the clinic review and be seen by the multidisciplinary team as usual. After the review, you will be asked to stay in your designated room for a little while longer.
- One of the CF physiotherapists or research team will then take 2 cough swabs, a saliva sample and then start the procedure for the clinic sputum-induction. This involves 3 additional samples over what you would normally give
- The clinic procedure involves hypertonic saline nebuliser and physiotherapy and will last about 20 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.

What does my child have to do?

- Your child will need to do their physiotherapy on the morning of clinic. You will need to be with them, so it will mean getting up just a little bit earlier than usual. The procedure at home will need to be done before breakfast, just when your child has woken up.

- In clinic your child will be guided through the procedure by our physiotherapist. Please check with the physiotherapist before giving your child something to eat in clinic, so that they can get the timing right.
- This clinic appointment may take a little longer than normal.

What are the possible disadvantages and risks of taking part?

- All of the procedures being used in this trial are part of your everyday physiotherapy regimen. The sputum-induction procedure is a very safe and well tolerated procedure, just like normal physiotherapy, but on this occasion your child will need to do it twice in one morning, and collect a sample for analysis at the end of each procedure.

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 sputum induction at home should become part of routine care for older children. There are no immediate benefits for your child personally, from taking part in this trial, but should any organisms be identified from any of the samples taken, then appropriate treatment will be prescribed.

What happens when the research trial stops?

- This research trial is planned to run over three years.
- Once we have obtained a sample from your child, you and your child have made your contribution to the trial.
- As the trial lasts for three years it may be that you are approached again at subsequent 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.

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

- You are free to withdraw your child from the trial at any time, including while he/she is performing the sputum-induction test, and this will not affect the future care of your child. Any data relating to your child's involvement in the trial will then be destroyed immediately, but samples and data analysed already will be used in the trial. You will also be asked whether you wish for any stored research samples that you may have already provided to be destroyed.

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

- Cardiff and Vale UHB is the organisation sponsoring this trial and is based in the United Kingdom.
- The sponsor will need to use information from your child's medical records for this research project.
- This information will include your
    - Name
    - Date of birth
    - UHW hospital number
    - Clinical information relating to your CF healthcare
- People will use this information to do the research or to check your records to make sure that the research is being done properly.
- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
- The sponsor will keep all information about you safe and secure.

- Once the trial is finished, the sponsor will keep some of the data so they can check the results. They will write reports in a way that no-one can work out that you took part in the trial.

What are your choices about how your information is used?

- You can stop being part of the trial at any time, without giving a reason, and we will just keep information about you that we already have.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our GDPR generic leaflet available from: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for- generic-information-document/
- by asking one of the research team
- by sending an email to the sponsor's data protection officer at: cav.ig.dept@wales.nhs.uk.

What will happen to the samples that my child provides?

Use of samples for this trial

- The samples you provide will be sent to the microbiology labs in Public Health Wales and processed in the normal way.
- Some of the samples you provide will be frozen at the hospital and stored for research.
- At a later date, all your child's frozen research samples will be transferred to researchers that we are collaborating with in the Department of Biosciences in Cardiff University. The samples will be used to look at the microbiome – this is the collection of good and bad organisms that live together in the lungs. This will include DNA extraction from the samples. Using the microbiome in cystic fibrosis is an important growing field of research and may help us change treatments in the future. The DNA that is extracted will be stored securely in a DNA archive in the Department of Biosciences and will be used in ongoing research projects.
- Some of your child's samples may be retained for a longer period of time and may be used in future research within Cardiff and Vale UHB, Cardiff university, within the UK or abroad. The samples will not be used within the commercial sector. At this stage we do not know what the research will involve but some of it could include more research on bacteria and further research on lung inflammation. Some may include looking at the genes of bacteria, but there will be no studies looking at your own genetic make-up. These mucous samples will be stored in the Department of Biosciences within Cardiff University. These samples will all be destroyed at the end of the trial.
- Your samples will never be sold, be used in commercial studies or be used in human genetic research or animal research.

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 trial and any samples remaining at the end of the trial will be destroyed.

What will happen to the data collected about my child in this trial

- This data will be kept by the investigators (your clinical team) and may be used in future longitudinal studies where patients are asked to contribute further samples. Such a study will help us learn how things change over time.

What will happen to the results of this trial?

- We intend to publish the trial 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. You and your child will be notified by letter with results and a link to access the publication in full.

Who is organising and funding the research?

- This trial has been organised by Dr Julian Forton and funded through the Children and Young Adult Research Unit (CYARU) at The Children's Hospital for Wales in Cardiff, and is supported by a Grant from the American Cystic Fibrosis Foundation

Who has reviewed the trial?

- All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect the interests of the participants. This trial has been reviewed by an NHS Independent Research Ethics Committee, Wales REC 7and also by the Cardiff and Vale University Health Board, as research Sponsor.

What if there is a problem?

- If you have a concern about any aspect of this trial, 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 through the NHS Complaints Procedure. via the Cardiff and Vale University Health Board Concerns Department (02921 836318; concerns@wales.nhs.uk)
- 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

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. You can contact us on 02920743530 or 02920744891

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