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# Induced sputum in children with cystic fibrosis

**Submission date**
03/01/2018

**Recruitment status**
No longer recruiting

**Registration date**
10/01/2018

**Overall study status**
Completed

**Last Edited**
06/08/2024

**Condition category**
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Cystic fibrosis (CF) is an inherited condition where the lungs and digestive system become clogged with mucus. 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, the child is often asked to give a cough swab, so that a sample of their 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 mucus 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. This study tests 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 the 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. The aim of this study is to compare the induced sputum test to a cough swab, a throat swab and a nasal swab. If the child is going to have a bronchoscopy because their doctor feels he/she needs one, then the results will be compared to the results of the bronchoscopy as well. The aim is to find out just how beneficial induced sputum really is, if it is done just once in the year, as part of the annual review, over and above the many cough swabs that are taken over the year. 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 study needs to be done before using the induced sputum technique routinely in patients with CF, to make sure that the procedure is well tolerated and also that it makes a worthwhile contribution to improving healthcare.

Who can participate?
Patients aged 6 months to 18 years with cystic fibrosis undergoing bronchoscopy under the care of South, West and Mid Wales Paediatric CF centre

What does the study involve?
One of the CF physiotherapists takes a cough swab, a throat swab and a nasal swab and then starts the procedure for induced sputum. Oxygen levels and heart rate are monitored during the procedure. If the child is over 7 years of age then he/she is asked to do a lung function test

before the procedure starts. The procedure involves a salty nebuliser (hypertonic saline) which lasts about 15 minutes. After each 5 minute period, the physiotherapist makes an assessment of the chest and gives appropriate physiotherapy or guides the child through breathing exercises to try and mobilise secretions. Any secretions are collected either into a pot, or by suction from the back of the throat. Lung function is tested again at the end of the procedure if appropriate. The final step is to take another cough swab.

What are the possible benefits and risks of participating?
The main benefit of this study is for the CF community as a whole, to find out 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 is prescribed. All of the procedures used in this study are already used by doctors in the treatment of children. Sometimes the salty nebuliser can make the child cough and some children can wheeze. Generally it is well tolerated in all age groups.

Where is the study run from?
Noah’s Ark Children’s Hospital for Wales (UK)

When is the study starting and how long is it expected to run for?
March 2011 to June 2019

Who is funding the study?
NISCHR Academic Health Science Collaboration (UK)

Who is the main contact?
Dr Julian Forton

# Contact information

### Type(s)
Scientific

### Contact name
Dr Julian Forton

### Contact details
The Children's Hospital for Wales
Cardiff University School of Medicine
Cardiff
United Kingdom
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

14615

# Study information

### Scientific Title
The contribution of induced sputum sampling to surveillance of lower respiratory tract microbiology in children with Cystic Fibrosis.

### Study objectives
The Cystic Fibrosis Sputum Induction Trial (CF-SpIT) is prospective internally-controlled interventional single-centre trial in children with Cystic Fibrosis trial designed to test sputum-induction as an infection diagnostic for bacterial sampling in children with cystic fibrosis. The study aims to compare pathogen yield from sputum-induction, with concurrent standard cough swab, 1-lobe BAL, the gold standard 2-lobe BAL, and also to comprehensive 6-lobe BAL in order to identify the relative contribution of each approach.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
South East Wales Research Ethics Service (Committee C), 06/01/2012, ref: 11/WA/0334

### Study design
Non-randomised; Interventional

### Primary study design
Interventional

### Secondary study design
Non randomised study

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
See additional files

### Health condition(s) or problem(s) studied
Specialty: Children, Primary sub-specialty: Respiratory and Cystic Fibrosis

### Interventions
Sputum induction will be paired with routine interventions for bacterial surveillance in children with cystic fbrosis, so that paired comparisons between sputum induction and standard approaches for pathogen detection may be performed.

In stage 1, sputum induction is compared to paired cough swab. Sputum induction is performed immediately after cough swab. Patients are recruited in outpatient clinic or as an inpatient prior to receiving IV antibiotics.

In stage 2, sputum induction is compared to bronchoalveolar lavage (BAL). This will be performed in a subgroup of patients who have been recruited into stage 1, and who were also attending for a clinically indicated bronchoscopy and bronchoalveolar lavage (BAL). Specifically, sputum induction will be performed within the 24 hours prior to bronchoscopy and BAL, and compared to paired 1-lobe BAL, 2-lobe BAL, and 6-lobe BAL.

### Intervention Type
Other

### Primary outcome measure
Stage 1: relative pathogen detection from sputum induction compared with cough swab
Stage 2: relative pathogen detection from sputum induction compared to 1-lobe BAL, gold standard 2-lobe BAL and 6-lobe BAL

### Secondary outcome measures
No secondary outcome measures

### Overall study start date
01/03/2011

### Completion date
30/06/2019

## Eligibility

### Key inclusion criteria
1. Diagnosis of cystic fibrosis
2. Under the care of South, West and Mid Wales Paediatric CF centre
3. Age 6 months – 18 years
4. Either gender
5. Attending for clinically indicated bronchoscopy (stage 2)
6. Not on treatment course of antibiotics

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants

Planned Sample Size: 200; UK Sample Size: 200

### Key exclusion criteria
1. Clinical grounds as defined by attending consultant
2. Previous serious reaction to hypertonic saline nebulisation

### Date of first enrolment
20/02/2012

### Date of final enrolment
31/12/2018

## Locations

### Countries of recruitment
United Kingdom

Wales

### Study participating centre
**Noah's Ark Children's Hospital for Wales**
Heath Park
Cardiff
United Kingdom
CF14 4XW

## Sponsor information

### Organisation
University Hospital of Wales

### Sponsor details
c/o Prof. Christopher Fegan
R&D Director
R&D Office
2nd Floor TB2
Cardiff
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### Sponsor type
Hospital/treatment centre

### ROR

https://ror.org/04fgpet95

# Funder(s)

**Funder type**
Government

**Funder Name**
NISCHR Academic Health Science Collaboration

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**
30/06/2019

**Individual participant data (IPD) sharing plan**
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

**IPD sharing plan summary**
Other

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version V2 | 11/12/2014 | 21/05/2018 | No | Yes |
| Participant information sheet | version V2 | 11/12/2014 | 21/05/2018 | No | Yes |
| Protocol file | version V3 | 03/01/2018 | 21/05/2018 | No | No |
| Results article | results | 01/06/2018 | | Yes | No |
| Other publications | fungal diversity | 01/08/2024 | 06/08/2024 | Yes | No |