ISRCTN11220163 https://doi.org/10.1186/ISRCTN11220163

Investigating outcome measures for trials of airway clearance techniques in adults with cystic fibrosis

Submission date
19/09/2016

Recruitment status
No longer recruiting

Registration date
19/09/2016

Overall study status
Completed

Last Edited
01/08/2023

Condition category
Respiratory

[X] 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 which causes the lungs and digestive system to become blocked with mucus. It is caused by a faulty gene, which is responsible for controlling the movement of water and salts in and out of cells. This leads to a buildup of sticky mucus which clogs the lungs and airways causing breathing difficulties and lung infections, and the digestive system which affects the way food travels through and the ability to absorb nutrients from it. Most people with CF experience problems with lung function and usually recommended to complete chest physiotherapy (also known as airway clearance techniques) as part of their daily routine. Traditionally the effect of these techniques, clinically and in research, have been assessed by how each patient feels during and after completing the technique, alongside changes in lung function (using a test called FEV 1, which tests how much air a person can exhale in one second), amount of sputum cleared (a mixture of saliva and mucus coughed up) and oxygen saturations (the amount of oxygen circulating around the body). Although these tests have been used historically, there is now some debate about whether they are the best measure to actually show the effect of airway clearance. Recent technological developments have seen some new tests developed which may give a more detailed picture into the short term effects of airway clearance techniques. The aim of this study is to compare the traditional measures of sputum cleared, FEV1 and oxygen saturations with these new tests.

Who can participate?
Patients with CF who are 16 years or over and who are registered as patients of the Royal Brompton Hospital.

What does the study involve?
The study involves attending two study visits in a random order. One study visit involves completing a maximum of 60 minutes chest physiotherapy using a breathing technique called Active Cycle of Breathing (ACBT), which involves normal relaxed breathing, deep breathing and huffs to clear sputum. The other study visit involves 60 minutes of rest in a comfortable position. Before and after the physiotherapy or rest, participants complete the traditional and new tests. These include:

1. Lung function (also called spirometry): the technique involves taking a deep breath and then blowing out through the machine as hard as possible for as long as possible
2. Lung clearance index (LCI): a technique which involves breathing quietly through a tube whilst wearing nose clips
3. Impulse oscillation system: a non-invasive technique where you breathe normally through a mouthpiece whilst wearing a nose clip, into a machine which produces small pressure vibrations (oscillations)
4. Oxygen saturation monitoring: completed by wearing a probe on a finger throughout the session.
5. Sputum collection: clearing any sputum created during the session into a special pot which is weighed at the end of the session and will then discarded appropriately
6. Electrical impedance tomography: involves wearing a belt around the chest which has electrodes attached to it
7. Participant questionnaire: asks the participants views on the tests completed during the visit

What are the possible benefits and risks of participating?
Participants benefit from being taught airway clearance techniques that they may wish to use in the future. There are no notable risks involved with participating.

Where is the study run from?
Royal Brompton Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2016 to October 2021

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Gemma Stanford
g.stanford@rbht.nhs.uk

Contact information

Type(s)
Public

Contact name
Mrs Gemma Stanford

ORCID ID
https://orcid.org/0000-0001-6967-6883

Contact details
Research Fellows Office
Dept of Cystic Fibrosis
South Parade
Royal Brompton Hospital
Sydney Street
London
United Kingdom

SW3 6NP
+44 20 7352 8121 ext 4028
g.stanford@rbht.nhs.uk

Additional identifiers

Protocol serial number
31428

Study information

Scientific Title
Improving outcome measures for physiotherapy trials of airway clearance in adults with cystic fibrosis

Study objectives
The aim of this study is to compare historical outcome measures (sputum weight and forced expiratory volume in 1 second) for airway clearance techniques with new measures (electrical impedance tomography, lung clearance index, impulse oscillometry) to find out whether there is a more scientific measure of ACT effect.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Chelsea Research Ethics Committee, 18/07/2016, ref: 16/LO/0995

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Physical, Management of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cystic fibrosis

Interventions
Participants are randomised to one of two groups using a computerised randomisation programme, which means they attend two study visits in a random order. The visits take place up to 1 month apart.

Study visit 1: Participants complete the airway clearance technique the Active Cycle of Breathing (ACBT) for a maximum of 60 minutes. ACBT is a breathing technique which includes normal relaxed breathing, deep breathing and huffs to clear sputum. Participants will be fully taught this by a specialist CF physiotherapist.

Study visit 2: Participants undergo up to 60 minutes of rest, in which they sit in a comfortable position and can complete any tasks which are non-active (such as reading/using internet etc.)

The length of the ACT and rest periods will be pre-defined by the individual participants usual airway clearance regime and will be in-between 30 and 60 minutes, with both periods in both study visits matched.

Before and after the physiotherapy or rest period, participants undergo the outcome measures of spirometry, LCI and IOS. During the session they will undergo EIT monitoring via an electrode belt round their chest, oxygen saturation monitoring via a finger probe and will be asked to spit any sputum cleared into a special pot which will be weighed after the period ends. At the end of each study visit the participant will be asked to complete a questionnaire asking their opinions of the outcome tests completed.

There is no additional follow up following the end of the second study visit.

Intervention Type
Other

Primary outcome(s)
1. Forced expiratory volume in 1 second (FEV1) is measured using spirometry immediately before and after the trial condition on each study visit
2. Lung clearance index (LCI) is measured using a multiple breath washout test immediately before and after the trial condition on each study visit
3. Impulse Oscillometry (IOS) is measured by a relaxed breathing test immediately before and after the trial condition on each study visit
4. Sputum weight is measured by weighing the amount of sputum expectorated during the treatment session immediately after the trial condition on each study visit
5. Electronic impedance tomography is measured during the treatment via an electrode belt around the chest, with measurements before, after and during the trial condition on each study visit

Key secondary outcome(s))
1. Patient opinion of the outcome measure tests are measured using a questionnaire designed for the purpose of this study at the end of each study visit
2. Lung function tests (FVC, FEF 25, FEF 50, FEF 75) are completed using a spirometer before and after the trial condition in each study visit
3. Oxygen saturation is measured via a finger probe during the trial condition on each study visit

Completion date
31/10/2021

Eligibility

Key inclusion criteria
1. Diagnosis of Cystic Fibrosis (confirmed by standard criteria)
2. Aged 16 years or over
3. Registered as patients of the Royal Brompton Hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
68

Key exclusion criteria
1. Evidence of pulmonary exacerbation within 3 weeks prior to screening
2. Any change in a chronic treatment/prophylaxis regimen for CF or CF-related condition within 4 weeks of visit Current infective exacerbation or reduction in lung function requiring therapeutic intervention
3. Current moderate haemoptysis (greater than streaking in the sputum)
4. Current dependency on positive pressure support with ACT Previous history of spontaneous rib fractures
5. Pregnancy Inability to give consent for treatment or measurement
6. Current dependency upon non-invasive ventilation Current dependency upon oxygen therapy

Date of first enrolment
26/09/2016

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Brompton Hospital
Sydney Street, London
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
Royal Brompton & Harefield NHS Foundation Trust

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/10/2020	08/10/2020	Yes	No

Abstract results	Presented at North American Cystic Fibrosis Conference	01/10/2022	01/08/2023	No	No
HRA research summary			26/07/2023	No	No