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Use of 3-helium MRI scanning to determine efficacy of chest physiotherapy in cystic fibrosis

Submission date	Recruitment status	[ ] Prospectively registered
28/09/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/09/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/05/2017	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof C J Taylor

Contact details
Academic Unit of Child Health
Floor C, Stephenson Wing
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
United Kingdom
S10 2TH
+44 (0)114 271 7304
c.j.taylor1@sheffield.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0220184922

Study information

Scientific Title
Use of 3-helium MRI scanning to determine efficacy of chest physiotherapy in cystic fibrosis

Study objectives
The aim of this study is to confirm the efficacy of chest physiotherapy in promoting airway mucus clearance in cystic fibrosis (CF).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
We have previously shown that 3-helium MRI scanning provides a reliable and reproducible means of imaging the chest of CF. The technique is well tolerated in children as young as 5 years and can show changes in both lung structure and function without exposing the subjects to the risks of radiation. We proposed to use 3-helium MRI scanning to demonstrate the efficacy of airway clearance techniques and to compare different types of chest physiotherapy. Children with CF attending the Regional CF Centre at Sheffield Children's Hospital will be recruited into an open study. 3-helium MRI scanning will be performed before and after a session of chest physiotherapy administered by a trained physiotherapist.
Subjects will be randomised to receive one of three different methods of airway clearance, all in routine use in this clinic.
Changes in the lung fields and dynamic changes in lung function will be assessed from the MR images using an established scoring system. Assignments will be performed by an independent observer blinded to the method of chest physiotherapy employed. Changes in MR score will be compared with conventional methods of lung function testing (spirometry) and the degree of

change correlated with the patients' general condition (Shwachmann and Chrispin Norman scores) derived from their annual review data.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in dynamic lung function as demonstrated by 3-helium MR scanning, post chest physiotherapy

Secondary outcome measures
Further demonstration of the use of 3-helium scanning to relate structural to functional change in the lung

Overall study start date
17/08/2006

Completion date
31/05/2007

Eligibility

Key inclusion criteria
1. Patients with CF
2. Aged <5 years
3. Able to perform spirometry

Participant type(s)
Patient

Age group
Child

Upper age limit
5 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
Patients undergoing a significant respiratory exacerbation sufficient to prevent lung function testing.

Date of first enrolment

17/08/2006

Date of final enrolment
31/05/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Unit of Child Health
Sheffield
United Kingdom
S10 2TH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Sheffield Children's NHS Foundation Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration