

A pilot study: do physiotherapy joint and muscle movement techniques improve forced expiratory volume in one second (FEV1) in adults with cystic fibrosis?

Submission date 28/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/12/2011	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0201189486

Study information

Scientific Title

Study objectives

Do gentle mobilisations to the bones of the rib cage and treatment of the muscles in the surrounding areas improve lung function (forced expiratory volume in one second) in adults with cystic fibrosis?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by Brompton, Harefield & NHLI Ethics Committee on 27/11/2006. REC reference number: 06/Q0404/81.

Study design

Randomised controlled pilot study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: Cystic fibrosis

Interventions

The Patient Advocate for Cystic Fibrosis, Royal Brompton & Harefield NHS Trust, the Senior Research Fellow in Physiotherapy, Dr Jennifer Pryor, and Senior Medical Consultant of the Department of Cystic Fibrosis, Professor Margaret Hodson, have participated in the formulation of the proposal. Professor Margaret Hodson, Dr Khin Gyi and Dr Sarah Elkin have agreed that their patients may be invited to participate in the study when it has received ethical approval.

Hypothesis:

The inclusion of a series of physiotherapy joint and muscle movement techniques (musculoskeletal) techniques to current optimal care for the treatment of people with cystic fibrosis will lead to short term improvements in lung function, posture and exercise capacity.

Methodology:

1. Written informed consent will be obtained for all subjects before entering the study.
2. Up to twenty patients will be randomised to a control group, to continue with their normal optimal care, or to a treatment group where they will receive musculoskeletal physiotherapy sessions once a week, for six weeks, at Royal Brompton Hospital in addition to their current optimal care.
3. An independent observer (blind to the subject's randomisation) will, after consent is signed, collect the baseline data, undertake the tests for exercise capacity, the measurements for posture and chest wall mobility, and administer the qualitative questionnaires for pain and for quality of life related to physical functioning.
4. The independent observer will then undertake repeated measurements of lung function, exercise capacity, posture, chest wall mobility, and administer the qualitative questionnaires for

pain and for quality of life related to physical functioning for all subjects at week three, six and twelve.

5. Full lung function tests will be undertaken in the Lung Function Laboratory (with the physiologist blind to the subject's randomisation) at baseline and after the six-week treatment period. When possible the subject's annual review lung function data will be used as the baseline measurement, to avoid duplication of these tests.

6. At the end point of the study subjects will be asked to complete a questionnaire.

The study will take place over twelve weeks from recruitment to final assessment. The treatment and control groups will attend four times for a total of one hour for assessment. The treatment group will also attend six treatment sessions which will take up to one hour. Two of those sessions will be on the same day as the independent measurements and will therefore take approximately two hours for the treatment group.

Statistical analysis:

The statistical analysis has been discussed with Mr Michael Roughton, Statistician, Royal Brompton & Harefield NHS Trust and Imperial College London and his advice taken.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

For the treatment group, outcome measures will be taken 30 minutes after treatment. For the control group these will be taken 15 to 30 minutes after arrival for assessment. The primary outcome measure will be forced expiratory volume in one second.

Key secondary outcome(s)

1. Other measures of lung function: forced vital capacity, peak expiratory flow rate, residual volume as a percent of total lung capacity
2. Modified shuttle test, monitoring oxygen saturation and heart rate and Borg CR10 scale of perceived exertion
3. Visual analogue scale for pain: a qualitative subjective assessment using a 10-centimeter scale
4. The Cystic Fibrosis Quality of Life Questionnaire, section one: physical functioning (Questionnaire I)
5. Flexi curve measurements of posture in standing
6. Chest wall excursion measurements using a tape measure for the circumference of the chest wall at axilla (armpit) and xiphisternal (lower chest) level
7. A questionnaire using a series of visual analogue scales with room for individual comment (Questionnaire II)

Completion date

09/07/2008

Eligibility

Key inclusion criteria

Added June 2008:

1. Reported postural changes, stiffness, discomfort and/or pain of musculoskeletal origin in the thoracic spine or chest wall
2. Diagnosis of cystic fibrosis (confirmed by genotype or a sweat sodium concentration of >70mmol/l or sweat chloride of >60mmol/l)
3. Sixteen years of age or over
4. Patients in a stable clinical state with lung function at the time of entry that is within 10% of the mean of the last two recordings (separated by at least one month).
5. Forced Expiratory Volume in 1 second (FEV1) \geq 30% predicted at time of entry to the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Added June 2008:

1. Evidence of a current respiratory exacerbation (worsening) as defined by Thornton et al. 2004
2. Cor pulmonale (right heart failure)
3. Low bone density (Z score < -3)(WHO Study Group 1994)
4. Previous history of spontaneous fractures
5. Past history of spinal fracture or other known arthropathic (joint) or spinal disease process
6. Currently undergoing musculoskeletal (physiotherapy, chiropractic or osteopathic) treatment
7. Pregnancy
8. Inability to give consent
9. Current enrolment in another research trial

Date of first enrolment

14/12/2006

Date of final enrolment

09/07/2008

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Royal Brompton & Harefield NHS Trust
London

United Kingdom
SW3 6NP

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type

Government

Funder Name

Royal Brompton and Harefield NHS Trust (UK)

Funder Name

No External Funding

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2011		Yes	No