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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

Registration date
28/09/2007

Overall study status
Completed

Last Edited
21/12/2011

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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)

Overall study start date
14/12/2006

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) ≥30% predicted at time of entry to the study

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
20

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 arthopathic (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
England

United Kingdom

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

Sponsor details
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Sponsor type
Government

Website
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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

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

Study outputs

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