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A pilot study to determine whether increasing oxygen flow rate or oxygen percentage through a fixed performance mask relieves breathlessness in patients with cystic fibrosis

Submission date
29/09/2006

Recruitment status
Stopped

Registration date
29/09/2006

Overall study status
Stopped

Last Edited
06/10/2011

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
N0226167746

Study information

Scientific Title

Study objectives
To compare whether changing oxygen flow or oxygen percentage through a fixed performance mask relieves breathlessness in patients with cystic fibrosis.

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Cystic fibrosis

Interventions
Cohort of stable CF Patients. Patients will perform a maximal bicycle ergometric exercise test on room air (under supervision of a specialist CF physiotherapist and doctor) to determine work rate & associated peak respiratory flow rate. VAS is assessed each minute to specifically determine degree of breathlessness. Following the exercise test VAS is assessed in recovery.

Patients are rested and randomly assigned one of three exercise tests over two days. These exercise tests use either an increasing oxygen concentration mask (flow rate remains the same). Relief of breathlessness will be determined by VAS scoring.

Added Seyember 2008: trial stopped due to lack of resources.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Increasing oxygen flow rate is beneficial to breathless patients

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2005

Completion date
30/12/2007

Reason abandoned (if study stopped)
Lack of resources

Eligibility

Key inclusion criteria
1. Cystic fibrosis patients aged over 16
2. Clinically stable
3. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
20 patients to be recruited from the Manchester Adult Cystic Fibrosis Unit.

Key exclusion criteria
Patients having respiratory exacerbation

Date of first enrolment
01/07/2005

Date of final enrolment
30/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Manchester Adult Cystic Fibrosis Centre
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
South Manchester University Hospitals NHS Trust (UK), 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