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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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Increasing oxygen flow rate is beneficial to breathless patients

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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
United Kingdom

England

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

Funder(s)

Funder type
Government

Funder Name
South Manchester University Hospitals NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration