Inspiratory muscle training in patients with Chronic Obstructive Pulmonary Disease (COPD)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited 17/09/2012	Condition category Respiratory	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Ms Lorna Johnson

Contact details

King's College Hospital Medical School Kensington Campus Camden Hill Road London United Kingdom W8 7AH +44 (0)20 7737 4000 lorna.johnson@kcl.ac.uk

Additional identifiers

Protocol serial number RDC01621

Study information

Scientific Title

Study objectives

The aim of this study is to investigate the effects of the POWERbreathe on respiratory muscle strength and endurance in people with COPD and also to assess the effects of IMT on breathlessness, functional exercise capacity and quality of life. The results of this study will provide evidence to enable healthcare professionals to advise their patients about the value of this device and may support the introduction of this or similar devices as a therapy for people with COPD.

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease

Interventions

Not provided at time of registration

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Mean changes in respiratory muscle strength (cms H2O), respiratory muscle endurance (peak power [cms H2O] and duration [seconds]), shuttle walk distance (metres), Borg scores for breathlessness and CRDQ will be compared between groups using an unpaired t-test or analysis of covariance. Any changes in respiratory muscle strength and endurance will be compared with changes in shuttle walk distance and CRDQ scores using correlation.

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/03/2002

Eligibility

Key inclusion criteria

- 1. 80 non-hypercapnic patients with moderate (forced expiratory volume [FEV] <40%) will be recruited from consultant hospital and community chest clinics.
- 2. All patients will be receiving optimum medical management and will have been stable for at least 4 weeks prior to their initial assessment.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

- 1. Hypercapnia (PaCO2 >45 mmHg)
- 2. Any patient who is unsuitable for magnetic stimulation (pacemakers, artificial heart valves, metal prosthesis).

Date of first enrolment

01/03/2000

Date of final enrolment

01/03/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre King's College Hospital Medical School London United Kingdom W8 7AH

Sponsor information

Organisation

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (UK)

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?
Abstract results		01/12/2003		No	No