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The use of a portable positive airway pressure device to relieve shortness of breath after exercise

Submission date	Recruitment status	[_] Prospectively registered
22/06/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/07/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/01/2017	Respiratory	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name used to refer to a number of progressive devastating and debilitating lung diseases, which includes chronic bronchitis, emphysema and chronic obstructive airways disease. People that have COPD typically feel breathless after physical activity, have a persistent cough with phlegm and suffer frequently from chest infections. Feeling short of breath can lead to inactivity and muscle deconditioning in patients with COPD. Positive airway pressure (PAP) can relieve shortness of breath and improve exercise tolerance (the amount of exercise that they are able to do). This study examines the effect of PAP delivered by a battery powered handheld device to COPD patients after exercise to relieve shortness of breath.

Who can participate?
Aged at least 18 with diagnosed COPD but able to do mild exercise.

What does the study involve?
Participants are randomly allocated into one of three groups. They are all then asked to do some mild exercise. Those in group 1 are then provided with the portable PAP device to use after the exercise to ease breathlessness. Those in group 2 are provided with what looks like a portable PAP device, but it is nonfunctional (a SHAM device) to use after the exercise. Those in group 3 are asked to perform lip breathing after exercise. The time it takes to return to the shortness of breath experienced prior to exercise for each participant is determined. We anticipate that the time after exercise to return to baseline shortness of breath using the hand held device is shorter than that while using a SHAM device and pursed-lip breathing (PLB) after exercise. As a secondary outcome, we will evaluate the distance walked during exercise.

What are the possible benefits and risks of participating?
Other than possibly gaining a better understanding of their ability to exercise and contributing to general knowledge of strategies to address shortness of breath, participants will not benefit directly from enrolling in the study. Risks of study participation include breathing and general discomfort while exercising. Lung damage from the portable positive airway pressure device is a

remote possibility. Participants will be closely monitored during exercise and may request that the exercise activity be terminated. Patients with a history of lung damage from positive pressure devices are not eligible to participate.

Where is the study run from?
Pittsburgh Pulmonary Associates Ltd (USA)

When is the study starting and how long is it expected to run for?
April 2014 to October 2015

Who is funding the study?
Philips Respironics (USA)

Who is the main contact?
Mr William Hardy
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HRC-1510-ENGVB-SS

Study information

Scientific Title
Effect of intermittent positive air pressure in relieve of shortness of breath in COPD patients after exertion.

Study objectives
To determine whether intermittent positive airway pressure given after exercise to patients with COPD can shorten their shortness of breath recovery period

Ethics approval required
Old ethics approval format

Ethics approval(s)
Allendale Institutional Review Board (AIRB), 26/03/2015

Study design
Prospective, interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

Interventions
Participants are asked to undergo exercise session and then use one of the following to alleviate shortness of breath:
1. Portable battery powered positive airway pressure (PAP) device
2. Portable sham positive airway pressure device
3. Pursed lip breathing

Intervention Type
Device

Primary outcome measure
Time to return to baseline shortness of breath rating after exercise

Secondary outcome measures
Distance walked during exercise

Overall study start date
06/04/2014

Completion date
30/10/2015

Eligibility

Key inclusion criteria
1. Age ≥ 18
2. Ability to provide consent
3. COPD diagnosis with FEV1 < 55 and > 25 of predicted value
4. Perceived Shortness of Breath via the Modified Medical Research Counsel Dyspnea questionnaire (rating of 2 or greater)
5. Able to follow directions
6. Able to tolerate mild physical activity

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Subjects who are acutely ill, medically complicated or who are medically unstable as determined by the investigator
2. Suffering from COPD Exacerbation at time of data collection

Date of first enrolment
06/04/2015

Date of final enrolment
30/10/2015

Locations

Countries of recruitment
United States of America

Study participating centre

Pittsburgh Pulmonary Associates, Ltd
United States of America
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Sponsor information

Organisation
Philips Respironics

Sponsor details
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15146

Sponsor type
Industry

Website
www.respironics.com

ROR
https://ror.org/03kw6wr76

Funder(s)

Funder type
Industry

Funder Name
Philips Respironics (USA)

Results and Publications

Publication and dissemination plan
Submitted late breaking abstract to the 2015 European Respiratory Society meeting. Upon completing recruitment of approximatlely thirty (30) participants, a peer reviewed publication is anticipated.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration