ISRCTN81979106 https://doi.org/10.1186/ISRCTN81979106

An eight week pilot study to investigate the effect of oscillation device on breathlessness in patients with chronic obstructive pulmonary disease

Submission date
21/03/2016

Recruitment status
No longer recruiting

Registration date
24/05/2016

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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. There is no cure for the condition, but making lifestyle changes (such as stopping smoking) and taking medications (inhalers and/or tablets) can alleviate symptoms. This study aims to investigate the effect of a high frequency airway oscillatory (HFAO) device on breathlessness in patients with COPD. The effects of this device will be measured using a series of questionnaires, exercise testing and measurement of respiratory muscle strength.

Who can participate?
Adult aged at least 40 and diagnosed with COPD.

What does the study involve?
The study involves two visits to hospital. At the first visit, the participants are assessed to see whether they are eligible to take part. They are given a number of questionnaires to complete that assess, for example, quality of life, breathlessness and anxiety and depression. They also undergo lung function tests, fitness tests and tests on respiratory muscles strength. The participants are then taught how to use the HFAO device and are asked to use it three times a day for five minutes at a time over the next eight weeks. They are contacted by telephone weekly to discuss any issues with the device and to see whether they are still using it (checking compliance). They are also asked to fill in a daily diary of their use of the device. After the eight weeks, all participants undergo the same assessments as they did at the start of the study.

What are the possible benefits and risks of participating?
The risks associated with the device are minimal. Benefits include being provided with the Aerosure device and manual to keep after the study has ended. Participants will also have the

opportunity to discuss their condition with a health care professional. The information collected from this study may help in to reducing breathlessness in patients with COPD in the future. Participants will be reimbursed for travel and parking costs.

Where is the study run from?
University Hospitals of Leicester (UK)

When is the study starting and how long is it expected to run for?
April 2016 to December 2016

Who is funding the study?
Actegy LTD

Who is the main contact?
Miss Enya Daynes
enya.daynes@uhl-tr.nhs.uk

Contact information

Type(s)
Public

Contact name
Miss Enya Daynes

ORCID ID
http://orcid.org/0000-0003-0127-1649

Contact details
Respiratory Biomedical Research Unit
Glenfield Hospital
Leicester
United Kingdom
LE3 9QP
01162502758
enya.daynes@uhl-tr.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
201676

Study information

Scientific Title
An eight week pilot study to investigate the effect of High-Frequency Airway Oscillation on breathlessness in patients with Chronic Obstructive Pulmonary Disease: a single arm interventional trial

Acronym
HFAO in COPD- Pilot

Study objectives
1. To test the hypothesis that patients training with a HFAO device for 8 weeks will have reduction in dyspnoea compared to baseline.
2. To test the hypothesis that patients training with a HFAO device for 8 weeks will show improvements in exercise capacity, cough frequency and intensity and dyspnoea at rest and upon exertion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Central Research Ethics Committee, 24/05/2016, ref: 16/LO/0924

Study design
Single centre single arm trial design administering medical device intervention

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
An Aerosure device will be issued to all participants in the trial. This is a high frequency airway oscillatory device to be used up to three times per day in order to gain an insight into the training effect to reduce breathlessness and improve quality of life.

The study involves two visits to hospital. The initial visit will determine eligibility and conduct baseline measurements which will include: Chronic respiratory questionnaire, Hospital anxiety and depression score, London Chest Activity of Daily living Score, Leicester Cough

Questionnaire, COPD Assessment Test, Incremental Shuttle Walk Test, Endurance Shuttle Walk Test, Spirometry and Inspiratory and expiratory max testing. Participants will be taught how to use the device and required to use it for 8 weeks in duration, three times a day for 5 minutes at a time or equivalent. Participants will be contacted by telephone weekly to discuss any issues with the device and record compliance. They will be required to retain a daily diary of usage. Participants will return after 8 weeks to repeat baseline measurements. At this stage they will have completed the trial. They will have the option to attend a dissemination event to share the results and gain feedback on the trial.

Intervention Type
Device

Primary outcome measure
Breathlessness at baseline and after 8 week of HFAO, measured using the Chronic respiratory Questionnaire (CRQ) Dyspnoea domain

Secondary outcome measures
1. Exercise endurance at baseline and after 8 week of HFAO, measured using the incremental and endurance shuttle walk test
2. Quality of life at baseline and after 8 week of HFAO, measured using the CRQ fatigue, mastery and emotion domains, COPD Assessment Test (CAT), Leicester Cough Questionnaire, London Chest Activities of Daily Living Questionnaire
3. Breathlessness pre and post exercise testing at baseline and 8 weeks of HFAO, measured using the Borg Breathlessness scale
4. Anxiety and depression at baseline and after 8 week of HFAO, measured using the Hospital Anxiety and Depression Scale
5. Inspiratory and expiratory muscle strength at baseline and after 8 week of HFAO, measured using lung function testing
6. Patient experience of trial measured in dissemination event discussion at the end of the trial (estimated October/November 2016)
7. Adherence of device use measured using daily diaries

Overall study start date
20/04/2016

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, aged 40 years or above
3. Confirmed diagnosed of COPD
4. MRC Score of 3 or more. (walk slower than people of the same age on the level or stops for breath when walking at own pace on the level)
5. Able to read and write in English

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Significant disease (other than COPD) that could cause dyspnoea or exercise limitation
2. Contraindications for exercise (unstable cardiovascular disease; hypertension etc, a full list is described by the American College of Sports Medicine and is routine deployed)
3. Inability/unwillingness to use the device
4. Contraindications to using HFAO device (including severe right heart failure with hypotension), current severe haemoptysis, ineffective cough, rib fractures, pregnancy, current or recent pneumothorax, epilepsy, current pulmonary embolism, oesophageal varices, recent thoracic, upper gastro-intestinal tract or facial surgery)
5. Previously engaged in exercised based research or pulmonary rehab in the last 6 months.
6. Inability to secure informed consent
7. Those unable to communicate in full English will be excluded as the user manual is only available in English

Date of first enrolment
01/05/2016

Date of final enrolment
13/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester
Groby Road
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
University Hospitals of Leicester

Sponsor details
Trust HQ, Level 3, Balmoral Building
Leicester Royal Infirmary
Infirmary Square
Leicester
England
United Kingdom
LE1 5WW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Industry

Funder Name
Actegy LTD

Results and Publications

Publication and dissemination plan
The results of this study is intended to be published in international journals and presented at conferences- to be confirmed. The results will also inform the main study which will commence after the completion of the pilot study.

Intention to publish date
31/01/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/05/2018	24/01/2019	Yes	No
HRA research summary			28/06/2023	No	No