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Oxygen for Muscles in COPD (OM-COPD)

Submission date
31/01/2013

Recruitment status
No longer recruiting

Registration date
31/01/2013

Overall study status
Completed

Last Edited
28/05/2020

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 is a lung condition often related to smoking, where the lung becomes damaged, and a number of manifestations outside the lung may be seen. One area which can be affected in COPD is skeletal muscle. The reasons for this are not wholly clear but may relate to stress on the muscle as a result of inflammation and problems with oxygenating the muscle adequately. This study aimed to elucidate some of the mechanisms behind muscle disease in COPD by examining muscle biopsies from patients when using oxygen, and when not using oxygen, comparing the two conditions, and assessing markers of inflammation at these times.

Who can participate?
Adults aged between 25-85 with chronic obstructive pulmonary disease.

What does the study involve?
Initially, participants in the study are assessed for the degree to which their blood oxygen falls when they exercise. They then have a muscle biopsy taken from the leg.They are then randomly assigned to be given oxygen to inhale for up to 4 hours a day for 12 weeks or a placebo (air containing the normal amount of oxygen) for up to 4 hours a day for 12 weeks. After each 12 week period, another muscle biopsy is taken. At specific time points, each participant is also asked to complete questionnaires to assess their mental health, quality of life and how active they are at home, as well as have blood tests to look at markers of inflammation. Throughout the study both patients and investigators do not know to the type of gas that they are breathing.

What are the possible benefits and risks of participating?
Possible benefits of participating include the patients feeling better when using the oxygen. The possible harms largely related to the muscle biopsy, which can cause pain and bruising.

Where is the study run from?
Heart of England NHS Foundation Trust, Birmingham (UK)

When is the study starting and how long is it expected to run for?
July 2012 to October 2013

Who is funding the study?
Linde Healthcare

Who is the main contact?
Dr Alice Wood
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2011-003595-36

IRAS number

ClinicalTrials.gov number
NCT01722370

Secondary identifying numbers
12180

Study information

Scientific Title
Can muscle dysfunction in COPD be altered by oxygenation in patients with intermittent hypoxia on exertion?

Acronym
OM-COPD

Study objectives
Patients with chronic obstructive pulmonary disease (COPD) may develop low oxygen levels, because of damage to their lungs. Long term oxygen therapy (LTOT) is given for at least 15 hours per day, and has established indications and benefits in COPD. However, the indications for and benefits from ambulatory oxygen supplementation (oxygen just when walking or exercising) are less well understood, in part due to heterogeneity of previous study designs, and lack of long term follow up.

We propose a pilot study of supplementary ambulatory oxygen in COPD, structured in the same manner as one of the larger studies to date in this condition, but with some key differences. Firstly, our study design will allow us to ascertain mechanisms of disease by measuring their degree of systemic inflammation pre and post oxygen supplementation, and measuring changes in gene expression in muscles by means of microarray profiling. Secondly, our study will utilise follow up of clinical parameters including home activity monitoring to ascertain medium/long term benefits of oxygen supplementation in a real life setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands NRES, Edgbaston, ref: 11/WM/0337

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Respiratory; Subtopic: Respiratory (all Subtopics); Disease: Chronic obstructive pulmonary disease

Interventions
Participants were randomly allocated to one of two initial groups:
1. Intervention arm - Ambulatory oxygen: Inhaled oxygen given for up to 4 hours/day at 2l/min via cylinder
2. Control arm - Placebo, Inhaled gas given at 2l/min, from cylinder for up to 4 hours/day. Is equivalent in oxygen content to medical air.

The study used oxygen delivered at a rate of 2l/min via nasal cannulae from a cylinder, carried by the patient, and compared to a control, which was a gas mix equivalent to air, delivered in the same manner. This was used for up to 4 hours per day, specifically only when the patient was mobilising. Activity was monitored at home to see how much mobilising they did. As a crossover study the intervention compared the treatment between phases in each individual rather than conducting group comparisons. The treatment was given for 12 weeks, and then crossed over to a further 12 weeks of control. The crossover was randomised and double blinded so some patients received intervention first and others received the control arm first.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Gene expression from quadriceps muscle biopsies, as measured by microarray and confirmed by PCR, compared between a 12 week period of treatment with air and oxygen, used on ambulation only.

Secondary outcome measures
1. 6MWT distance; Timepoint(s): 0,3, 6 months
2. Arterial blood gas (ABG); Timepoint(s): 0,3,6 months
3. Home activity level; Timepoint(s): 0, 6, 12, 18, 24 weeks
4. Quality of Life (QOL) - CAT score; Timepoint(s): 0,6,12,18,24,30 weeks

Overall study start date
20/07/2012

Completion date
31/10/2013

Eligibility

Key inclusion criteria
1. Spirometry: post bronchodilator [ratio of the forced expiratory volume in the first one second to the forced vital capacity of the lungs (FEV1/FVC) <0.7]
2. Six-minute walk test (6MWT): desaturation to less than 90% on walking
3. Blood gas: does not meet criteria for LTOT i.e. pO2 >7.3KPa or >8KPa if co-existent cor pulmonale
4. Male & Female; Upper Age Limit 85 years ; Lower Age Limit 25 years

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
UK Sample Size: 25

Total final enrolment
25

Key exclusion criteria
1. Imobile due to other medical conditions
2. On LTOT
3. Unable to understand or retain information
4. Uncontrolled anginal symptoms
5. Evidence of potential harm from oxygen supplementation on previous capillary gases or dejours test specifically a rise in CO2 after being given oxygen that is of a clinically significant magnitude

Date of first enrolment
20/07/2012

Date of final enrolment
31/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Heart of England NHS Foundation Trust
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
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England

United Kingdom
B15 2TT

Sponsor type
University/education

Website
http://www.birmingham.ac.uk

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Industry

Funder Name
Linde Healthcare

Results and Publications

Publication and dissemination plan
Paper of results currently under submission

Added 21/01/2019:
2018 results published in thesis: http://etheses.bham.ac.uk/8369/

Intention to publish date
31/08/2016

Individual participant data (IPD) sharing plan
Anonymised patient level data for the genomic work is accessible from the gene expression omnibus link: http://www.ncbi.nlm.nih.gov/geo/query/acc.cgi?acc=GSE90154.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			28/05/2020	No	No
HRA research summary			28/06/2023	No	No