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Oxygen during activities in patients with lung scarring

Submission date	Recruitment status	[_] Prospectively registered
21/03/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/03/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/12/2018	Respiratory	

Plain English summary of protocol

Background and study aims
Fibrotic Lung Diseases (FLD) are a group of long-term diseases which affect the way the lungs work. The most common form is idiopathic pulmonary fibrosis (IPF), with approximately 5,000 new cases diagnosed every year in the UK, and an average survival of two-three years after diagnosis. These conditions are characterised by widespread scarring inside the lungs (fibrosis), which prevent them from expanding fully. As the lung tissue becomes scarred and thicker, the lungs lose their ability to transfer oxygen into the bloodstream. This means that it can be difficult for a sufferer to get enough oxygen, as the amount that they can inhale is limited. The diagnosis tends to be made when a person becomes short of breath when exercise, which becomes progressively worse. Breathlessness triggerered by activity can often be associated with a drop in oxygen levels in the blood (oxygen desaturation) from the normal level (more than 94%) to a critical level (less than 88%). Giving patients supplemental oxygen can correct this desaturation however there are no international guidelines for oxygen therapy in FLDs. This study aims to explore the benefits of ambulatory oxygen (portable oxygen treatment that can be used during activities, such as walking).

Who can participate?
Adults with IPF or another FLD whose blood oxygen level falls below 88% in a six minute walk test.

What does the study involve?
Following a two week run-in period (to ensure the patients are stable), participants receive either ambulatory oxygen or no portable oxygen devices for two weeks in a random order. The ambulatory oxygen is provided for patients at home and is delivered through a nasal cannula (tube which has two prongs which are placed in the nose that oxygen flows through) which is attached to an oxygen container. During the two weeks when the patient is allocated to receive ambulatory oxygen, they are asked to use the oxygen during any activity that makes him/her breathless (such as walking, gardening, housework). During the two weeks when the patient is allocated no oxygen, they are asked to carry out their normal day to day activities with no portable devices. Patients are given an activity monitor (a small band to be placed around the arm that records the number of steps taken and intensity of physical activity) to wear during the second week of each two week period. Patients are also asked to wear an oximeter for 48 hours

(a portable device like a watch that continuously measures oxygen levels and heart rate) in the week when they are wearing the armband. In addition to this, patients are asked to complete a diary of daily activities and complete a few weekly questions on the amount of oxygen used. Participants complete a number of questionnaires at the start of the study and at the end of each two week study period about their breathlessness, quality of life and mobility.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
1. Interstitial Lung Disease, Unit Royal Brompton Hospital (UK)
2. Liverpool Interstitial Lung Fibrosis Service, University Hospital Aintree (UK)
3. Bristol Interstitial Lung Disease (BILD) Service, Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2013 to December 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2013-004355-20

IRAS number

ClinicalTrials.gov number
NCT02286063

Secondary identifying numbers
2013OE005B

Study information

Scientific Title
Randomised, controlled crossover trial to evaluate the Effects of Ambulatory Oxygen on health status in patients with Fibrotic Lung Disease (FLD)

Acronym
AmbOx

Study objectives
Ambulatory oxygen used during daily activities improves respiratory symptoms and quality of life in patients with fibrotic lung disease whose oxygen saturation drops<89% on a six minute walk test but who are not hypoxic on room air.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ref: 14/LO/0258

Study design
Multi-centre randomized crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Fibrotic lung diseases

Interventions
The study will consist of a four week randomized crossover trial of ambulatory oxygen for use during physical activity, by patients with fibrotic lung disease whose oxygen saturation drops to ≤88% during a six minute walk test (6MWT). At the start of the trial, the effects of ambulatory oxygen on 6 Minute Walk Test (6MWT) performances will be evaluated on oxygen and on air-filled canisters, with the patient blind to the contents of the canister, to assess whether oxygen-induced improvements in 6MWT parameters can predict its effectiveness in day to day life. The 6MWT is a well-established and highly reproducible test validated in ILD patients, with significant prognostic implications . Patients meeting eligibility criteria and deemed clinically stable at the end of a two week run in period, will be assigned in random order to two weeks on ambulatory oxygen or not during the baseline visit.

Optimal oxygen flow rates will be determined during the screening visit on the basis of the entry 6 minute walk test (6MWT) on O2, so as to maintain oxygen saturation ≥ 90 for at least half of the 6MWT, where possible. Following receipt of the treatment arm assigned during the baseline visits for two weeks, patients will cross-over to receive the alternative treatment for further two weeks. Supplemental oxygen will be obtained through the Home Oxygen Order Form (HOOF), supplied by the different oxygen companies depending on the region in England, as per standard NHS clinical practice. The light-weight portable oxygen gas cylinders will be used across sites to standardise mode of delivery.

Intervention Type
Other

Primary outcome measure
The difference between the two treatment arms in the total “health status” score as assessed by the King's Brief Interstitial Lung Disease (K-BILD) health status questionnaire at the end of each of the two week treatment periods.

Secondary outcome measures
Secondary outcomes will be measured at baseline, and at 2 and at 4 weeks. They include:
1. Dyspnoea scores, as assessed by the University of California, San Diego shortness of breath questionnaire
2. Respiratory-related quality of life scores, as assessed by the St George’s Respiratory Questionnaire (SGRQ)
3. Anxiety and depression scores, as assessed by the Hospital Depression and Anxiety Score (HDAS) questionnaire
4. Global patient assessment
5. Objective activity parameters, as assessed by Sensewear armbands (which will be worn by patients for one of two weeks in each treatment period)
6. 48 hour oximetry measures including oxygen saturation and heart rate (oximeter worn by the

patient for 48 hours during each of the two week intervention periods)
7. Patient reported hours of daily activity, as assessed by self-reported activity diaries, purpose-made for this trial
8. Patient reported oxygen cylinder use, cross-checked with oxygen company records where possible
9. In a subgroup of 20 patients, qualitative interviews conducted by a member of the research team trained in qualitative research, with the patients and their carers will take place at the end of the trial period, to gather information on patients' and carers' perspectives on the use of oxygen, its advantages and drawbacks

Overall study start date
01/04/2013

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1.Patients with a diagnosis of idiopathic pulmonary fibrosis (IPF), or with another fibrotic ILD
2. Aged between 18 and 99 years
3. Patients whose oxygen saturation (SaO2) at rest on room air is ≥94% and falls<88% on a baseline 6MWT (performed as part of their routine assessment)
4. Patients with stable symptoms and treatment during the period of four weeks prior to being recruited into the study, including the two week run in period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1.Patients expected to change treatment over the time course of the study, and those meeting criteria for long term oxygen therapy, i.e. hypoxic at rest
2.Patients with connective tissue disease-associated ILD or with sarcoidosis with musculoskeletal /joint involvement/symptoms will be excluded due to the potential impact in relation to day-to-day mobility
3.Patients with significant communication or other locomotor difficulties, and/or severe co-morbidities
4.Current smokers in view of the potential risks associated with use of supplemental oxygen

5.Pregnancy
6.History of symptomatic ischaemic cardiac disease (exertion-induced chest pain)
7.Anaemia, Hb<10g/dl

Date of first enrolment
01/08/2014

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Interstitial Lung Disease Unit
Royal Brompton Hospital
Sydney Street
London
United Kingdom
SW3 6NR

Study participating centre
Liverpool Interstitial Lung Fibrosis Service
Aintree Chest Centre
University Hospital Aintree
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United Kingdom
L9 7AL

Study participating centre
Bristol Interstitial Lung Disease (BILD) Service
Respiratory Medicine
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. Planned publication of trial results in international peer reviewed leading respiratory journals
2. Planned presentation of results at international respiratory meetings, as well to patient /public action and support groups

Intention to publish date

30/06/2018

Individual participant data (IPD) sharing plan

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	01/10/2018		Yes	No
HRA research summary			28/06/2023	No	No