ISRCTN22894945 https://doi.org/10.1186/ISRCTN22894945

Ambulatory oxygen improves the effectiveness of pulmonary rehabilitation in selected patients

Submission date
26/04/2010

Recruitment status
No longer recruiting

Registration date
13/05/2010

Overall study status
Completed

Last Edited
29/07/2013

Condition category
Respiratory

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Julia Bott

Contact details
The Respiratory Care Team
C/o Bournewood House
Guildford Road
Chertsey
United Kingdom
KT16 0QA

Additional identifiers

Protocol serial number
TC08/5

Study information

Scientific Title
The effectiveness of ambulatory oxygen versus room air during pulmonary rehabilitation in patients who are hypoxaemic on exertion and respond to supplemental oxygen at baseline

Study objectives

The aims of this prospective randomised controlled trial is to determine whether ambulatory oxygen during pulmonary rehabilitation provides additional benefit, compared with room air, for patients hypoxaemic only on exertion and who respond to supplemental oxygen at baseline. Additionally, to determine whether the degree of acute response to ambulatory oxygen predicted any additional benefit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Surrey Ethics Committee approved on the 7th August 2007 (ref: 07/H1109/89)

Study design
Prospective multicentre single blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic respiratory disease

Interventions
Patients randomised into two groups:
1. Ambulatory oxygen group exercise within pulmonary rehabilitation and at home using ambulatory oxygen
2. Room air group exercise within pulmonary rehabilitation and at home on room air

Secondary sponsor details:
Trevor Clay Memorial Fund (UK)
British Lung Foundation
73 - 75 Goswell Road
London EC1V 7ER

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Exercise tolerance measured using the Endurance Shuttle Walk Test pre- and post-pulmonary rehabilitation

Key secondary outcome(s))
1. Quality of life measured using the Self-Report Chronic Respiratory Questionnaire
2. Anxiety and depression measured using the Hospital Anxiety and Depression Scale
3. Function measured using the Surrey Information on Function Tool

All are questionnaires completed pre- and post-pulmonary rehabilitation.

Completion date
30/09/2009

Eligibility

Key inclusion criteria
Patients (aged 50 - 87 years, either sex) with chronic respiratory disease enrolled in pulmonary rehabilitation who have resting saturations greater than 92%, but desaturate by greater than 4% and to less than 90% on exertion and who then walk greater than 10% further with ambulatory oxygen during field exercise testing at baseline.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Already on oxygen therapy (long-term or ambulatory)
2. Those who do not desaturate significantly on exertion
3. Those who do desaturate but do not demonstrate benefit using ambulatory oxygen at baseline

Date of first enrolment
01/09/2007

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

The Respiratory Care Team
Chertsey
United Kingdom
KT16 0QA

Sponsor information

Organisation
Surrey Community Health (UK)

Funder(s)

Funder type
Charity

Funder Name
Surrey Community Health (UK)

Funder Name
British Lung Foundation (UK) - Trevor Clay Memorial Fund research grant

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?
Results article	results	01/05/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes