

Ambulatory oxygen improves the effectiveness of pulmonary rehabilitation in selected patients

Submission date 26/04/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 13/05/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/07/2013	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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)

Primary study design

Interventional

Study design

Prospective multicentre single blind randomised controlled trial

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