

A double blind randomized study of oxygen versus medical air in oxygen naïve patients with refractory dyspnea and PaO₂ >55 mmHg

Submission date 29/03/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/05/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/10/2010	Condition category Respiratory	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00327873

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

O2 Breathe

Study objectives

Oxygen therapy is superior to air in relieving the sensation of breathlessness in palliative care patients with intractable dyspnoea and PaO₂ >55 mmHg

Null hypothesis: The provision of home oxygen in patients who do not meet the Australian national guidelines for domiciliary oxygen does not improve the subjective sensation of breathlessness.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Refractory dyspnea

Interventions

240 participants will be recruited through the palliative care, oncology, pulmonary, cardiology, and general medicine departments at five sites in Australia, two sites in the USA, and two sites in the UK. Participants will receive oxygen or medical air delivered at 2 liters per minute via concentrator and nasal cannulae. Participants are expected to use the treatment for more than 15 hours per day for 7 days. Concentrators will be delivered on the morning of Day 0 and retrieved on the morning of Day 7. Concentrator meters monitored by the company will provide

evidence of gas delivery. Participants may continue all normal medications and treatments that they are receiving including physical therapy, exercise, change in position, inhaled treatments, and suctioning. Participants can receive new therapies during the study as would normally be prescribed by their treating doctors. Baseline examination will include medical diagnoses, smoking history, previous experience with oxygen, medications, vital signs, pulse oximetry, Karnofsky performance status, physical examination, resting PaO₂, resting PaCO₂, hemoglobin, and a description of the breathlessness. Participants will complete a study log twice a day for nine days (days -2 to 7) about the sensation of dyspnea using a 0-10 numeric rating scale (NRS) twice a day, sleep disturbance, breathlessness in the past 24 hours on the NRS, percentage relief of dyspnea, drowsiness, nasal irritation, performance status, vital signs, functional impact, and quality of life (QOL). Functional impact will be measured on the 4-point categorical Modified Medical Research Council of Great Britain (MRC) dyspnea scale and the Dyspnea Exertion Scale (DES).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

0-10 Numeric rating scale for dyspnoea.

Secondary outcome measures

1. McGill Quality of Life Questionnaire
2. Modified Medical Research Council Dyspnoea Scale
3. Dyspnoea Exertion Scale
4. Descriptors of dyspnoea
5. Verbal descriptor scales for nausea, drowsiness, nasal irritation, anxiety, patient preference
6. Costs of oxygen/air usage during and following participation

Overall study start date

01/10/2004

Completion date

30/06/2007

Eligibility**Key inclusion criteria**

1. Adult patients with intractable dyspnea and PaO₂ >55 mmHg in the setting of terminal illness where the underlying cause has been maximally treated. A medical specialist must document that all identified reversible causes of the dyspnea have been treated. PaO₂ measurement must be in the last month.
2. Dyspnea can be at rest or with minimal exertion, as measured by a score of ≥ 3 on the Medical Research Council categorical dyspnea exertion scale
3. On stable medications over the prior week except routine 'as needed' medications
4. Prognosis of at least 1 month in the opinion of the treating physician

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

240

Key exclusion criteria

1. Meets international guidelines for long-term oxygen therapy with PaO₂ 56-59 mmHg i.e. symptomatic pulmonary hypertension with cor pulmonale
2. Hemoglobin <10.0 g/dl as measured within one month of baseline evaluation
3. PaCO₂ >50 mmHg
4. Confusion with Folstein Mini-mental Status Exam (MMSE) <24/30
5. Current oxygen therapy or continuous oxygen therapy in previous week
6. Actively smoking
7. Active respiratory or cardiac event in the previous 7 days, not including upper respiratory tract infections. Illness must be resolved for at least 7 days prior to baseline evaluation, as judged by a doctor involved in the care of the patient.
8. Previous respiratory failure induced by oxygen
9. Unable to give informed consent or complete diary entries

Date of first enrolment

01/10/2004

Date of final enrolment

30/06/2007

Locations

Countries of recruitment

Australia

United Kingdom

United States of America

Study participating centre

Southern Adelaide Palliative Services

Daw Park, South Australia

Australia

5041

Sponsor information

Organisation

Repatriation General Hospital (Australia)

Sponsor details

Daws Road

Daw Park

South Australia

Australia

5041

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04b0n4406>

Funder(s)**Funder type**

Research organisation

Funder Name

National Health and Medical Research Council (Australia)

Alternative Name(s)

NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

Funder Name

Cancer Council of Tasmania (Australia)

Funder Name

Duke Institute for Care at the End of Life (USA)

Funder Name

Doris Duke Charitable Foundation (USA)

Alternative Name(s)

Doris Duke Charitable Foundation, Inc., DDCF Trust, Doris Duke Foundation, DDCF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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	04/09/2010		Yes	No