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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
29/03/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
10/05/2005	Completed	[X] Results
Last Edited	Condition category	Individual participant data
07/10/2010	Respiratory	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

ClinicalTrials.gov (NCT)

NCT00327873

Protocol serial number

N/A

# Study information

#### Scientific Title

#### **Acronym**

02 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

#### Study type(s)

Treatment

#### 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(s)

0-10 Numeric rating scale for dyspnoea.

#### Key secondary outcome(s))

- 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

#### 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

# Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Αll

#### 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

United Kingdom

Australia

United States of America

Study participating centre Southern Adelaide Palliative Services Daw Park, South Australia Australia 5041

# Sponsor information

#### Organisation

Repatriation General Hospital (Australia)

#### **ROR**

https://ror.org/04b0n4406

# Funder(s)

# Funder type

Research organisation

#### **Funder Name**

National Health and Medical Research Council (Australia)

#### Alternative Name(s)

National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, 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, The Doris Duke Charitable Foundation, DDCF, DDF

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

#### Location

United States of America

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

**Study outputs** 

Output type Details Date created Date added Peer reviewed? Patient-facing?

Results article results 04/09/2010 Yes No