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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

Registration date
10/05/2005

Overall study status
Completed

Last Edited
07/10/2010

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
Dr Amy Abernethy

Contact details
Southern Adelaide Palliative Services
700 Goodwood Road
Daw Park, South Australia
Australia
5041
+61 8 8275 1732
amy.abernethy@duke.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00327873

Secondary identifying numbers

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

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