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Does the use of a handheld fan improve intractable breathlessness?

Submission date 19/05/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/06/2008	**Overall study status** Completed	
Last Edited 16/08/2010	**Condition category** Signs and Symptoms	

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

Secondary identifying numbers
OCRD2005/04

Study information

Scientific Title

Study objectives
The use of a handheld fan directed to the cheek does not relieve intractable breathlessness in patients with chronic maximally treated cardiac and respiratory disorders or advanced cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Peterborough and Fenland Local Research Ethics Committee on the 6th September 2005 (ref: 05/Q0106/64).

Study design
Randomised controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Breathlessness from malignant or non-malignant cause

Interventions
1. Use of handheld fan directed to the face (active treatment)
2. Use of handheld fan directed to the leg (control arm of study)

As per the protocol, the interventions of fan directed to face (active treatment) or to leg (control arm) were for 5 minutes each treatment. Washout periods were 10 minutes. There were no follow ups after the treatment and washout periods were completed as the study comprised a single intervention of treatments carried out in randomised order followed by washout after each treatment. The total carried out over a total duration of less than 1 hour.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Decrease in visual analogue scale of greater than 10 mm after use of handheld fan directed to face.

The primary outcome measure was a recording of visual analogue score for breathlessness. This was measured at baseline (time zero), after 5 minutes use of fan directed to face or leg, at completion of subsequent 10 minute washout period, after 5 minutes use of second treatment (fan to face or leg) and after final 10 minute washout period.

Secondary outcome measures
No secondary outcome measures

Overall study start date
13/12/2005

Completion date
18/10/2007

Eligibility

Key inclusion criteria
1. Patient is chronically breathless
2. Dyspnoea Exertion Scale (DES) levels 2 or above
3. Any diagnosis causing intractable breathlessness
4. Aged greater than 30 years, either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
49

Key exclusion criteria
1. Anaemic patients with haemoglobin (Hb) less than 10 g/l
2. Patients with fever greater than 38.0°C in last 24 hours
3. Patients on continuous oxygen
4. Patients requiring short burst oxygen therapy whilst completing the study
5. Patients with diseases or treatment affecting the trigeminal nerve supply
6. Patients on beta blockers
7. Patients with known autonomic neuropathy
8. Patients with peripheral vascular disease
9. Patients with cerebral disease or receiving cerebral radiotherapy

10. Patients with known severe cardiac or intrapulmonary arterio-venous shunts
11. Patients unable to understand or cooperate with study
12. Patients who do not wish to participate in the study
13. Patients whose disease is not maximally medically treated

Date of first enrolment
13/12/2005

Date of final enrolment
18/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Palliative Care, Oncology Centre, Box 193
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Trust R&D Department, Box 277
Addenbrooke's Hospital
Hills Road
Cambridge
England
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CB2 0QQ

Sponsor type
Hospital/treatment centre

Website
http://www.addenbrookes.org.uk/

ROR

https://ror.org/04v54gj93

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (UK) - fans used in the study were donated and investigator time and equipment used was already available within the department

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	01/05/2010		Yes	No