Does the use of a handheld fan improve intractable breathlessness?

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

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

Protocol serial number 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

No secondary outcome measures

Completion date

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

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

United Kingdom

England

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

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (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

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