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Randomised controlled trial of closed circuit Continuous Positive Airway Pressure (CPAP) and open circuit CPAP with a Boussignac valve for the treatment of acute pulmonary oedema.

Submission date
30/09/2004

Registration date
30/09/2004

Last Edited
10/07/2009

Recruitment status
No longer recruiting

Overall study status
Completed

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0013101032

Study information

Scientific Title

Study objectives
This study will seek to determine whether the Boussignac valve system is as effective as conventional CPAP using a Drager CF800 circuit.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory: Acute pulmonary oedema

Interventions
The patient will be randomised to one of two groups:
1. CPAP with the closed circuit Drager CF800 system
OR
2. CPAP with the open circuit Vygon Boussignac valve system

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

The main outcome measure will be the PaCO2 at 30 and 60 minutes. Other outcome measures will be PaO2 at 30 and 60 minutes, need for intubation, and tolerance of mask/circuit.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2001

Completion date
31/12/2003

Eligibility

Key inclusion criteria
Patients with acute pulmonary oedema attending Accident and Emergency (A&E). We intend to recruit 50 patients to allow for recruitment errors and drop outs etc.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
50

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/2001

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Acute Medicine
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guy's and St Thomas' NHS Trust (UK)

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	01/06/2005		Yes	No