The effect of continuous positive airway pressure (CPAP) and non-invasive positive pressure ventilation (NIPPV) in acute cardiogenic pulmonary oedema (ACPO)

Submission date	Recruitment status	[X] Prospectively registered
25/04/2003	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	Condition category	Individual participant data
02/08/2010	Circulatory System	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 01/43/01

Study information

Scientific Title

Acronym

3CPO

Study objectives

To assess the clinical effectiveness of non-invasive ventilation against standard therapy alone

More details can be found at http://www.hta.ac.uk/project/1338 Protocol can be found at http://www.hta.ac.uk/protocols/200100430001.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not requested 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

Cardiovascular diseases: Heart disease

Interventions

Continuous Positive Airway Pressure (CPAP) versus Non-Invasive Positive Pressure Ventilation (NIPPV)

Please note that, as of 28 January 2008, the anticipated end date of this trial was updated from 31 December 2007 to 30 April 2008.

Please note that as of 12th June 2007, the anticipated end date of this trial was extended to 31st December 2007 (Anticipated end date provided at time of registration: 30 June 2006). Recruitment to this trial was closed on 30 April 2007.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Added on the 12th June 2007:

- 1. NIV versus standard therapy: seven-day mortality
- 2. CPAP versus NIPPV: seven-day mortality or intubation

Secondary outcome measures

Added on the 12th June 2007:

- 1. Physiology
- 2. Side-effects including Myocardial Infacrtion (MI)
- 3. Cost-effectiveness

Overall study start date

01/06/2003

Completion date

30/04/2008

Eligibility

Key inclusion criteria

- 1. More than 16 years
- 2. Acute Cardiogenic Pulmonary Oedema (ACPO) principal clinical complaint
- 3. Confirmed diagnosis of ACPO

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

1200 (this information was added on the 12th June 2007)

Key exclusion criteria

- 1. Patients needing immediate life-saving interventions
- 2. Inability to provide informed consent

Date of first enrolment

01/06/2003

Date of final enrolment

30/04/2008

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre Emergency Department

Edinburgh United Kingdom EH16 4SA

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House Quarry Hill Leeds United Kingdom LS2 7UE +44 (0)1132 545 843 Sheila.Greener@doh.gsi.gov.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/en/index.htm

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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	10/07/2008		Yes	No
Results article	results	01/07/2009		Yes	No
Results article	results	01/08/2010		Yes	No