ISRCTN07448447 https://doi.org/10.1186/ISRCTN07448447

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

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
02/08/2010

Condition category
Circulatory System

[X] 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
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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