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Ambulance CPAP: use, treatment effect and economics feasibility study

Submission date	**Recruitment status**	[X] Prospectively registered
12/08/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/08/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/09/2023	Respiratory	

Plain English summary of protocol

Background and study aims
Acute respiratory failure is a common and life-threatening medical emergency that often results in long hospital stays or expensive intensive care admissions. It occurs when heart or lung disease suddenly develops or worsens and leads to the patient being unable to maintain oxygen levels in their blood. When this happens the patient is at high risk of death and needs emergency treatment. Paramedics currently provide oxygen delivered at normal pressure by a loose fitting face mask. Continuous positive airway pressure (CPAP) is a potentially useful treatment that could be delivered by paramedics in an ambulance. It involves delivering oxygen under increased pressure through a tight-fitting face mask. Its use in hospital can reduce the risk of death in people with lung disease and improve breathing in people with heart disease. Small studies undertaken outside the UK have suggested that using CPAP in an ambulance may save more lives than delaying its use until arrival at hospital. However, it is uncertain whether this treatment could work effectively in NHS ambulance services, and if it represents good value for money. The aim of this study is to see whether it is possible and worthwhile to undertake a full-scale study comparing CPAP and standard oxygen treatment delivered by paramedics for acute respiratory failure, and if so, how we should do it.

Who can participate?
Adults aged over 18 with acute respiratory failure

What does the study involve?
Paramedics identify adults with acute respiratory failure when attending 999 emergency calls. Participants are randomly allocated to either receive CPAP or standard oxygen treatment. All the participants then undergo normal hospital treatment and are followed up for a month to see if they survive. The participants' quality of life, need for admission to intensive care, and length of stay in hospital are also measured. Additionally, the study measures how many adults are attended with acute respiratory failure, how many are entered into the study, the number who correctly receive CPAP treatment, and how many patients we can follow up to the end of the study. Paramedics are also surveyed to understand their experience of delivering CPAP and aspects of the research. Together these results indicate whether it is feasible and affordable to conduct a full-scale study of CPAP for acute respiratory failure, and inform how to design it.

What are the possible benefits and risks of participating?
CPAP may improve acute respiratory failure symptoms and outcomes. Also, the study may help to improve the treatment of people with acute respiratory failure in the future, making participation a positive experience. CPAP can cause feelings of claustrophobia. In rare cases CPAP can contribute to aspiration (vomiting, with vomit entering the lungs) or pneumothorax (collapsed lung). There are strict criteria for entering people into the study to minimise the chance of these risks. Any side effects occurring during the study are carefully monitored. Participants receive usual clinical care following random allocation and treatment. No further clinical risks are therefore expected during the study.

Where is the study run from?
West Midlands Ambulance Service NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2016 to February 2019

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
1. Dr Sam Keating (s.m.keating@sheffield.ac.uk)
2. Dr Gordon Fuller

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HTA 15/08/40

Study information

Scientific Title
The ACUTE (Ambulance CPAP: Use, Treatment Effect and Economics) feasibility study: a pilot randomised controlled trial of prehospital CPAP for acute respiratory failure

Acronym
ACUTE

Study objectives
Is it possible and worthwhile to undertake a full-scale study comparing continuous positive airway pressure (CPAP) delivered by paramedics to standard oxygen treatment for adults with acute respiratory failure? And if so, how should we do it?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/150840

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Leeds East Research Ethics Committee, 31/10/2016, ref: 16/YH/0406

Study design
Stand-alone randomised controlled pilot trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute respiratory failure (ARF)

Interventions
A stand-alone randomised controlled pilot trial will be conducted. Patients with acute respiratory failure will be identified by paramedics responding to 999 ambulance call and enrolled in the study.

Patients randomised to the intervention arm will receive treatment with CPAP, a form of noninvasive ventilation where oxygen is supplied to the upper airways at increased pressure through a tight-fitting mask. The O_two CPAP unit will be used: a lightweight, single use, low flow system. Patients randomised to the control arm will receive oxygen delivered at normal atmospheric pressure via nasal cannula, an air entrainment 'Venturi' mask, a simple face mask, or a non-rebreathing reservoir face mask. Patients in both trial arms will receive other standard pre-hospital and hospital treatments.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
O-Two CPAP unit

Primary outcome(s)
The following feasibility outcomes will be reported descriptively together with their 95% confidence interval:
1. Recruitment rate per 100,000 population per year (target 8, i.e. 120 across 1.5 million)
2. Proportion recruited in error and classified as violations or deviations (target 0% and ≤10%)
3. Adherence to the allocation schedule (target ≥90%)
4. Adherence to treatment in the CPAP arm (target ≥75%)
5. Retention at 30 days (target ≥90%)
6. Data completeness (target ≥90%)

Key secondary outcome(s))
Summary estimates of effectiveness outcomes will also be reported with 95% confidence intervals across the whole trial population using an as randomised analysis:
1. Proportion surviving to 30 days
2. Proportion undergoing endotracheal intubation by 30 days
3. Proportion admitted to critical care at any point up to 30 days
4. Mean and median length of hospital stay
5. Mean EQ-5D-3L (measured for each participant at baseline and at the 30-day follow-up)
6. Key elements of health-care resource use up to 30 days

Completion date
28/02/2019

Eligibility

Key inclusion criteria
1. Adults aged over 18
2. Acute respiratory failure defined as respiratory distress with peripheral oxygen saturation below BTS target levels (88% for patients with COPD, 94% for other conditions), despite supplemental oxygen

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
77

Key exclusion criteria
1. The time difference between being able to start prehospital CPAP and being able to start in-hospital CPAP is expected to be less than 15 minutes
2. Age < 18 years
3. Known to have terminal illness
4. Known pre-existing lack of capacity (confirmed by relatives, carers or documentary evidence, such as Lasting Power of Attorney)
5. Documented not for resuscitation status
6. Acutely incapacitated patients with valid advanced directive declining non-invasive ventilation or participation in research
7. The patient has an oxygen alert card
8. Anticipated inability to apply CPAP (e.g. facial deformity)
9. Respiratory failure due to chest trauma
10. Contraindication to CPAP (suspected pneumothorax, respiratory arrest, epistaxis, vomiting, hypotension)

Date of first enrolment
01/08/2017

Date of final enrolment
31/07/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
West Midlands Ambulance Service NHS Foundation Trust
Trust Headquarters, Millennium Point
Waterfront Business Park
Waterfront Way
Brierley Hill
West Midlands
United Kingdom
DY5 1LX

Sponsor information

Organisation
University of Sheffield

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the trial Manager Dr Sam Keating (s.m.keating@sheffield.ac.uk).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/07/2020	28/07/2020	Yes	No
Results article	results	01/02/2021	05/02/2021	Yes	No
Results article	Nested diagnostic accuracy and agreement study	01/12/2020	18/09/2023	Yes	No
Protocol article	protocol	18/06/2018		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet		12/08/2016	12/08/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes