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Airway Management Feasibility Study (REVIVE-Airways)

Submission date	Recruitment status
24/05/2012	No longer recruiting
Registration date	**Overall study status**
24/05/2012	Completed
Last Edited	**Condition category**
21/01/2016	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] 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
11962

Study information

Scientific Title
Randomised comparison of the effectiveness of the Laryngeal Mask Airway Supreme, i-gel and current practice in the initial airway management of pre-hospital cardiac arrest: a feasibility study (REVIVE-Airways)

Acronym
REVIVE

Study objectives
Cardiac arrest occurs when the heart suddenly stops beating, and is one of the most extreme medical emergencies. Outcomes remain poor with most patients not surviving. Effective treatments for cardiac arrest are limited and represent a major unmet health need. The main treatment is cardiopulmonary resuscitation (CPR), which is a combination of rescue breathing and chest compressions. Prompt and effective CPR is essential to prevent damage to the brain and other organs. Minimising interruptions of continuous chest compressions improves survival.

Current evidence supports a change in rescue breathing. Historically, placing a breathing tube in the windpipe (tracheal intubation) was viewed as the best pre-hospital airway management in cardiac arrest, but we now know that attempting intubation can lead to significant complications and prolonged interruptions in chest compressions. As a result, national recommendations advocate using newer airway devices (supraglottic airway devices: SADs). These are quicker to insert and cause minimal interruption to chest compressions. However the best type of SAD and their effectiveness in comparison to current practice is unknown.

This research study is a preliminary investigation to determine whether our proposed design will allow us to compare the two most promising SADs (i-gel and LMAS) with current practice during pre-hospital cardiac arrest. This will be done by dividing paramedics working in Great Western Ambulance Service, and who agree to take part, into three groups. Each group will be given structured education on CPR and rescue breathing. One group will be taught to use the i-gel, one group the LMAS and one group will continue as usual. If this research design works, and produces useful results, we will proceed to a large scale study to determine whether one of these approaches improves patient survival. This will shape future guidelines and benefit cardiac arrest patients in the UK and internationally.

More details can be found at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=11962

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC 31/10/2011 ref: 11/EE/0407

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Injuries and Emergencies

Interventions
i-gel Arm, Patients attended by a paramedic who has been randomised to this arm will receive resuscitation according to the Resuscitation Council (UK) and JRCALC Advanced Life Support Guidelines, with the exception that the i-gel supra-glottic airway device will be used initially to manage the airway. All standard advanced life support interventions will be provided including drug administration, defibrillation and chest compressions as required.; LMAS Arm, Patients attended by a paramedic who has been randomised to this arm will receive resuscitation according to the Resuscitation Council (UK) and JRCALC Advanced Life Support Guidelines, with the exception that the Laryngeal Mask Airway Supreme (LMAS) supra-glottic airway device will be used initially to manage the airway. All standard advanced life support interventions will be provided including drug administration, defibrillation and chest compressions as required.

Usual Practice Arm, Patients attended by a paramedic who has been randomised to this arm will receive resuscitation according to the Resuscitation Council (UK) and JRCALC Advanced Life Support Guidelines. All standard advanced life support interventions will be provided including drug administration, defibrillation and chest compressions as required.; Follow Up Length: 3 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Assess if it is possible to conduct a full-scale study

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/03/2012

Completion date
28/02/2013

Eligibility

Key inclusion criteria
Paramedics:
Working in Great Western Ambulance Service and consenting to participate

Patients:
1. Have had a cardiac arrest in the pre-hospital setting
2. Attempted resuscitation is appropriate according to standard guidelines
3. Aged 18 years or older
4. Target Gender: Male & Female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 534; UK Sample Size: 534; Description: The sample size of 534 comprises 150 paramedics and 384 patients

Key exclusion criteria
Patients:
1. Less than 18 years old
2. Estimated weight is less than 50 kg
3. Mouth opening is less than 2 cm
4. The latter two exclusions have been applied because the SGAs evaluated in this trial are not designed for use in patients with low body weight or significantly reduced mouth opening.

Date of first enrolment
01/03/2012

Date of final enrolment
28/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Faculty of Health & Life Sciences
Bristol
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Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Protocol article	protocol	13/02/2013		Yes	No
Results article	results	01/02/2016		Yes	No