

Airway Management Feasibility Study (REVIVE-Airways)

Submission date

24/05/2012

Recruitment status

No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date

24/05/2012

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

21/01/2016

Condition category

Injury, Occupational Diseases, Poisoning

☐ 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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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Faculty of Health & Life Sciences

Bristol

United Kingdom

BS16 1DD

Sponsor information

Organisation

University Hospitals Bristol NHS Foundation Trust (UK)

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

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	01/02/2016		Yes	No
Protocol article	protocol	13/02/2013		Yes	No