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# Airway management in out of hospital cardiac arrest patients.

**Submission date**
22/07/2014

**Recruitment status**
No longer recruiting

**Registration date**
28/07/2014

**Overall study status**
Completed

**Last Edited**
19/04/2022

**Condition category**
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
A cardiac arrest occurs when the heartbeat and breathing stop suddenly. It is one of the most extreme medical emergencies. Health outcomes are poor; less than 1 in 10 patients survive to be discharged from hospital. The best initial treatment is cardiopulmonary resuscitation (CPR); a combination of rescue breathing and chest compressions. Prompt and effective CPR prevents damage to the brain and other organs, and maximises the chance that the heart will start beating again. Ensuring a clear airway, whilst interrupting chest compressions as little as possible, is essential for survival. At the moment, we do not know the best way for NHS ambulance staff to provide rescue breathing during an out of hospital cardiac arrest. Placing a breathing tube in the windpipe (tracheal intubation) has been considered the best method of airway management, but this can cause complications as well as interruptions in chest compressions. Recently national recommendations suggested using a newer method of airway management: the insertion of a supraglottic airway device (SAD). A SAD is a tube that sits on top of the voice box. These devices are already used during routine anaesthesia in hospitals and in emergency care. They are quicker to insert and cause less interruption to chest compressions compared to intubation, however the SAD may not stay in place as securely as a breathing tube and, if a patient vomits, stomach contents may get into their lungs causing further complications. The aim of the AIRWAYS-2 trial is to determine whether intubation or the best available SAD (called the i-gel) gives the best chance of recovery following a cardiac arrest that takes place out of hospital (out of hospital cardiac arrest - OHCA).

Who can participate?
Paramedics employed by one of the four ambulance trusts who have agreed to support the study (South Western Ambulance Service NHS Foundation Trust, East of England Ambulance Service NHS Trust, East Midlands Ambulance Service NHS Trust , Yorkshire Ambulance Service NHS Trust). All out of hospital cardiac arrest patients attend by an AIRWAYS-2 paramedic are automatically enrolled in the study.

What does the study involve?
Paramedics who consent to take part in the study are allocated into one of two airway management pathway groups. Those in group A use intubation (where a breathing tube is placed in the windpipe) when administrating CPR. Those in group B use the i-gel device (where the

breathing tube sits on top of the voice box). Patients that survive the cardiac arrest are taken into hospital and information on their functional status and quality of life when they are discharged from hospital, and then three and six months after the cardiac arrest; patients that agree to active follow up are asked to complete patient questionnaires. At the end of the study we will compare treatment costs.

What are the possible benefits and risks of participating?
Paramedics will benefit from additional training in resuscitation, airway management and evidence based practice during the trial. We do not know whether the study will benefit OHCA patients but the information we get from this study will help improve the treatment of people who have an OHCA in the future.

Where is the study run from?
The University of the West of England and the Clinical Trial and Evaluation Unit, Bristol in collaboration with South Western Ambulance Service NHS Trust.

When is the study starting and how long is it expected to run for?
February 2015 to October 2018

Who is funding the study?
National Institute for Health Research, Health Technology Assessment (UK)

Who is the main contact?
Professor Jonathan Benger
jonathan.benger@uwe.ac.uk.

### Study website
https://airways2.blogs.bristol.ac.uk/

# 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 12/167/102; Sponsor: 13-034; Protocol Version: 1.0

# Study information

### Scientific Title
Cluster randomised trial of the clinical and cost effectiveness of the i-gel supraglottic airway device versus tracheal intubation in the initial airway management of out of hospital cardiac arrest

### Acronym
AIRWAYS-2

### Study objectives
The hypothesis is that the i-gel, a second-generation supra-glottic airway device, is superior to tracheal intubation in non-traumatic out of hospital cardiac arrest in adults, in terms of both clinical and cost effectiveness.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/12167102
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/130665/PRO-12-167-102.pdf

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NRES Committee South Central - Oxford C, 24/09/2014, ref: 14/SC/1219

### Study design
Parallel two-group multi-centre cluster randomised controlled trial and accompanying cost-effectiveness analysis

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

## Participant information sheet
Available on request

## Health condition(s) or problem(s) studied
Out of hospital cardiac arrest (OHCA)

## Interventions
Control group:
The current standard care pathway is tracheal intubation: the placement of a cuffed tube in the patient's trachea (windpipe) to provide oxygen to the lungs and remove carbon dioxide. Tracheal intubation is considered the gold standard of airway management, and is used universally in comatose survivors of cardiac arrest following their admission to hospital.

Intervention group:
The intervention being studied is the insertion of an i-gel, a second-generation SAD, as an alternative to tracheal intubation.

Aspects of management common to both groups:
For both the intubation and intervention group care will proceed as normal for OHCA patients enrolled in the trial, aside from the initial airway management. The trial intervention will cease after care is handed over to the medical team in hospital or the patient is recognised as life extinct by ambulance clinicians at scene. This will be a period of between 30 and 90 minutes.

Patients will then be followed up at hospital discharge, 3 and six months following the patients cardiac arrest.

## Intervention Type
Procedure/Surgery

## Primary outcome measure
The modified Rankin scale (mRS) score at hospital discharge, which incorporates survival to discharge and is widely used in OHCA research. Death scores 6, and mRS is usually presented dichotomously as good recovery (0-3) or poor recovery/death (4-6). We will collect survival and mRS at hospital discharge from routinely available clinical data with the prior permission of the Health Research Authority Confidentiality Advisory Group (CAG). However, other and longer-term outcomes are also important, and we will therefore seek consent from survivors (or a consultee according to the requirements of the Mental Capacity Act 2005 if the patient lacks capacity) to collect additional data at hospital discharge and 3 and 6 months after OHCA. We have chosen a 6-month final follow-up (compared to 3 in our feasibility study) because, whilst there are very few additional deaths between 3 and 6 months, cognitive function and quality of life continue to improve during this time.

## Secondary outcome measures
We will seek consent from survivors (or a consultee according to the requirements of the Mental Capacity Act 2005 if the patient lacks capacity) to collect additional data at hospital discharge and 3 and 6 months after OHCA.

All enrolled patients
1. Initial ventilation success, defined as visible chest rise.
2. Regurgitation/aspiration.
3. Loss of a previously established airway.

4. Actual sequence of airway interventions delivered.
5. Chest compression fraction.
6. Return of spontaneous circulation (ROSC).
7. Airway management in place when ROSC was achieved or the resuscitation was discontinued.
8. Economic data regarding expenditure and further healthcare contacts.

Patients who survive to admission to hospital (estimated 20% of enrolled patients)
9. Length of intensive care stay.
10. Length of hospital stay.

Patients who survive to hospital discharge (estimated 9% of enrolled patients)
11. Quality of life at hospital discharge.

Patients who survive beyond hospital discharge (estimated 8% of enrolled patients)
12. Modified Rankin scale at 3 and 6 months following OHCA.
13. Quality of life (using the EQ5D) at 3 and 6 months following OHCA.
14. Cognitive function (using the cerebral performance category) 3 and 6 months following OHCA.
15. Date of death, where this occurs during the trial.

### Overall study start date
01/02/2015

### Completion date
01/10/2018

# Eligibility

### Key inclusion criteria
Paramedic inclusion criteria:
1. Employed by one of the four participating ambulance trusts in general operational duties, and could therefore be despatched to attend an OHCA as the first or second paramedic to arrive on scene.

Patient inclusion criteria:
1. Patient known or believed to be 18 years of age or older
2. Must be in non-traumatic cardiac arrest outside hospital
3. Patient must be attended by a paramedic who is participating in the trial and is either the 1st or 2nd paramedic to arrive at scene.*1
4. Resuscitation is attempted by ambulance staff.*2

*1 The time and order of staff arrival is routinely collected by ambulance services. The participating paramedic will manage the patients airway, according to their allocation. If both the 1st and 2nd paramedic are participating in the trial, the patients airway will be managed according to the allocation of the 1st paramedic to arrive (usually designated as the attendant within the ambulance service).
*2 Circumstances in which resuscitation should and should not be attempted are described in national guidelines, but the frequency of attempted resuscitation in both arms will be regularly examined by the DMSC to identify any bias in the commencement of resuscitation attempts

### Participant type(s)

Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
We estimate each paramedic will attend 7 OHCA over a two-year recruitment period. We aim to recruit 1,300 paramedics to give approximately 9,070 OHCA patients enrolled in the trial.

### Total final enrolment
10819

### Key exclusion criteria
Paramedic exclusion criteria:
1. Paramedics working in non-clinical and managerial roles not routinely attending OHCA

Patient exclusion criteria:
1. Patient detained by Her Majesty's Prison Service
2. Previously recruited to the trial
3. Estimated weight <50 kg
4. Mouth opening <2 cm

The latter two exclusions have been applied because SADs are not designed for use in patients with low bodyweight or significantly reduced mouth opening. There is a risk of post-randomisation bias being introduced by these two exclusion criteria, but in our feasibility study only 2/711 patients (0.3%) were excluded on these grounds. We will monitor these exclusions, under the supervision of the DMSC, and should the exclusion rate exceed 1% we will take action to address this through enhanced training and supervision.

### Date of first enrolment
01/02/2015

### Date of final enrolment
13/02/2018

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre

**Bristol Royal Infirmary**
Bristol
United Kingdom
BS2 8HW

# Sponsor information

**Organisation**
South Western Ambulance Service NHS Foundation Trust (UK)

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**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/009dhvf97

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

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

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
We intend to disseminate our primary outcome in late Spring 2018. This will take the form of publication in a high-impact peer reviewed journal, as well as presentation at relevant conferences.
Our long term and secondary outcomes will also be published in high-impact peer reviewed journals in late 2018, with presentation at relevant conferences.

### Intention to publish date
01/01/2019

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from bristol-cteu@bristol.ac.uk.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 01/12/2016 | | Yes | No |
| Results article | results | 28/08/2018 | | Yes | No |
| Other publications | trial design and implementation | 08/02/2019 | | Yes | No |
| Results article | participant interview results | 01/04/2020 | 12/02/2020 | Yes | No |
| Results article | 3- and 6-month follow-up results | 01/12/2020 | 16/12/2020 | Yes | No |
| Results article | cost-effectiveness results | 11/06/2021 | 15/06/2021 | Yes | No |
| Results article | | 01/04/2022 | 19/04/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |