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Randomised trial comparing advanced airway management during in-hospital cardiac arrest

Submission date
03/05/2022

Recruitment status
No longer recruiting

Registration date
29/07/2022

Overall study status
Ongoing

Last Edited
21/01/2025

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether the insertion of a new type of airway device to restore breathing is more effective than the traditional technique of tracheal intubation for adults who have a cardiac arrest while in hospital.
Cardiac arrest occurs when the heart stops beating; it is an extreme medical emergency. If a patient in hospital has a cardiac arrest, their chance of surviving to leave hospital is less than one in four. Immediate chest compressions combined with rescue breathing improve the chances of survival. We do not know the best way for hospital staff to provide rescue breathing (airway management) during an in-hospital cardiac arrest. Traditionally, placing a breathing tube in the windpipe (tracheal intubation) has been considered the best method. However, inserting the tube requires specialist skills. A newer alternative is a supraglottic airway device, placed in the throat just above the voice box. Such devices are easier and quicker to use and require less training. However, they may protect the lungs less from damage by vomit and may not be as good at inflating the lungs. The International Liaison Committee on Resuscitation has highlighted an urgent need for research in this area.

Who can participate?
Patients aged 18 years and over who are experiencing an in-hospital cardiac arrest

What does the study involve?
Participants will be randomly allocated to one of these two types of airway management. The researchers will compare the degree of disability, survival rates, quality of life, use of NHS resources (e.g. hospital bed days and procedures) for all patients included in the trial. The research will cover each patient's hospital stay and 3 and 6 months after the cardiac arrest. Information will be collected primarily from hospital databases, to reduce the amount that patients need to do. It will be collected using postal questionnaires and routine data with the patient's consent. Treatment costs will be measured for each approach.

What are the possible benefits and risks of participating?
At the point of consent participants have already completed cardiac arrest treatment, so there

are no personal risks or benefits from continuing to participate in this study. The information collected will help to decide the best way to treat patients in the future and answer questions on which method is the most effective for keeping an open airway during a cardiac arrest.

here is the study run from?
University Hospitals Bristol and Weston NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2022 to December 2026

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
314379

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 314379, HTA - NIHR131533, CPMS 53015

Study information

Scientific Title

Randomised trial of the clinical and cost-effectiveness of a supraglottic airway device versus intubation in-hospital cardiac arrest

Acronym
AIRWAYS-3

Study objectives
During in-hospital cardiac arrest (IHCA), airway management with a supraglottic airway (SGA) device is clinically superior and cost-effective when compared with tracheal intubation (TI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/07/2022, Wales REC 1 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 785738; Wales.REC1@wales.nhs.uk), ref: 22/WA/0156

Study design
Multi-centre open-label pragmatic individually randomized parallel-group superiority trial and economic evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
In-hospital cardiac arrest that requires advanced airway management

Interventions
The researchers will be using a bespoke progressive web application (PWA) to randomise.

Intervention: A supraglottic airway device of the type used routinely in that hospital. During resuscitation the SGA will be placed according to the manufacturer's instructions, with end-tidal carbon dioxide monitoring wherever possible, following an initial period of bag-mask ventilation as required. Two attempts at SGA placement should be made. An attempt is defined as introducing a SGA past the teeth, and concludes when the SGA is removed from the mouth. If two attempts at SGA placement are unsuccessful treatment will proceed as dictated by the treating clinician (including tracheal intubation if indicated). If successful, the SGA should be used until resuscitation efforts cease or return of spontaneous circulation (ROSC) is achieved for >20 minutes, at which point further management will proceed as dictated by the treating clinician.

Comparator: Tracheal intubation. During resuscitation tracheal intubation should occur, with end-tidal carbon dioxide monitoring wherever possible, following an initial period of bag-mask ventilation as required. Two attempts at intubation should be made. An attempt is defined as introducing the laryngoscope past the teeth, and concludes when the laryngoscope is removed from the mouth, regardless of whether or not a tracheal tube is inserted. If two attempts at

tracheal intubation are unsuccessful subsequent treatment will proceed as determined by the treating clinician (including placement of a SGA if indicated). If successful, tracheal intubation should continue until resuscitation efforts cease or ROSC is achieved for >20 minutes, at which point further management will proceed as dictated by the treating clinician.

Both interventions are part of standard clinical care in the treatment of IHCA and there are no known additional risks to the participants above routine care.

Treatment duration: Until return of spontaneous circulation (ROSC) for >20 minutes or resuscitation efforts cease, after which the airway will be managed by the attending team as they feel appropriate.

Follow up duration: 6 months post in-hospital cardiac arrest.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
A supraglottic airway device of the type used routinely in that hospital

Primary outcome(s)
Functional status as measured by the modified Rankin Scale (mRS) at hospital discharge (or 30 days post-randomisation whichever is shorter)

Key secondary outcome(s))
1. Initial ventilation success measured using data collected from site staff into a bespoke application at baseline
2. Regurgitation/aspiration during resuscitation measured using data collected from site staff into a bespoke application at baseline
3. Return of spontaneous circulation (ROSC) >20 minutes measured using data collected from site staff into a bespoke application at baseline
4. ICU and hospital length of stay measured using data linkage from National Cardiac Arrest Audit (NCAA) at hospital discharge
5. Health-related quality of life measured using EQ5D-5L questionnaire at discharge, 3 and 6 months
6. Survival to hospital discharge, 3 months and 6 months measured using data linkage from NCAA and Office for National Statistics (ONS) death registry
7. Functional status (mRS) measured using the modified Rankin Scale (mRS) at 3 and 6 months

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Adult (known or believed to be age ≥18 years)
2. In-hospital cardiac arrest, attended by the hospital cardiac arrest team in response to a cardiac arrest call (2222 or equivalent), and including a clinician permitted to undertake tracheal

intubation and supraglottic airway placement so that either intervention can be delivered
3. Undergoing resuscitation and requiring advanced airway management in the opinion of the clinician managing the patient's airway

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 02/08/2024:

1. Patients who have a cardiac arrest outside hospital and who are transported to the hospital in ongoing cardiac arrest
2. People who are not a hospital inpatient (e.g. visitor, relative, staff or outpatient)
3. Patients already receiving advanced airway management (including a supraglottic airway device) at the time of eligibility assessment
4. Patients known to be pregnant
5. Patients with a functioning tracheostomy

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Previous exclusion criteria:

1. Patients in the emergency department
2. People who are not a hospital inpatient (e.g. visitor, relative, staff or outpatient)
3. Patients already receiving advanced airway management (including a supraglottic airway device) at the time of eligibility assessment
4. Patients known to be pregnant
5. Patients with a functioning tracheostomy

Date of first enrolment
01/09/2022

Date of final enrolment
31/12/2024

Locations

Countries of recruitment

United Kingdom

England

Wales

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
St. Michaels Hospital
Southwell Street
Bristol
United Kingdom
BS2 8EG

Sponsor information

Organisation
University Hospitals Bristol and Weston NHS Foundation Trust

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

The trial statisticians and Data Monitoring Committee (DMC) will have access to the dataset for the analysis of trial outcomes. Once the main analyses have been undertaken, de-identified individual participant data will be available to other investigators subject to the approval of data analysis plans and compliance with the University of Warwick standard operating procedures (SOPs) on Data Management and Sharing. Approval of data analysis plans will be the responsibility of the Trial Steering Committee (TSC) during the lifetime of the trial. Following study completion, the Chief Investigator and Warwick Clinical Trials Unit Data Sharing Committee will be jointly responsible for the approval of data analysis plans. The trial will comply with Data Sharing Policies that may be instituted by the NIHR during the lifetime of the project.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Protocol, design and implementation	18/07/2023	31/07/2023	Yes	No
HRA research summary			28/06/2023	No	No
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