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Design and implementation of the AIRWAYS-2 trial: A multi-centre cluster randomised controlled 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☆

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ABSTRACT

Health outcomes after out of hospital cardiac arrest (OHCA) are extremely poor, with only 7–9% of patients in the United Kingdom (UK) surviving to hospital discharge. Currently emergency medical services (EMS) use either tracheal intubation or newer supraglottic airway devices (SGAs) to provide advanced airway management during OHCA. Equipoise between the two techniques has led to calls for a well-designed randomised controlled trial.

The primary objective of the AIRWAYS-2 trial is to assess whether the clinical effectiveness of the i-gel, a second-generation SGA, is superior to tracheal intubation in the initial airway management of OHCA patients in the UK. Paramedics recruited to the AIRWAYS-2 trial are randomised to use either tracheal intubation or i-gel as their first advanced airway intervention. Adults who have had a non-traumatic OHCA and are attended by an AIRWAYS-2 paramedic are retrospectively assessed against eligibility criteria for inclusion.

The primary outcome is the modified Rankin Scale score at hospital discharge. Secondary objectives are to: (i) estimate differences between groups in outcome measures relating to airway management, hospital stay and recovery at 3 and 6 months; (ii) estimate the cost effectiveness of the i-gel compared to tracheal intubation. Because OHCA patient needs immediate treatment there are several unusual features and challenges to the design and implementation of this trial; these include level of randomisation, the automatic enrolment model, enrolment of patients that lack capacity and minimisation of bias.

Abbreviations: CAD, computer aided dispatch; CAG, Confidentiality Advisory Group; CPR, cardiopulmonary resuscitation; CRF, case report form; CTEU, Clinical Trials and Evaluation Unit; EEAST, East of England Ambulance Service NHS Trust; EMAS, East Midlands Ambulance Service NHS Trust; EMS, Emergency Medical Services; HES, Hospital Episode Statistics; ICC, intraclass correlation; ILCOR, International Liaison Committee on Resuscitation; JRCALC, Joint Royal Colleges Ambulance Liaison Committee; mRS, modified Rankin Scale; NICE, National Institute for Health and Care Excellence; NHS, UK National Health Service; OHCA, out of hospital cardiac arrest; QALY, quality adjusted life year; RCT, randomised controlled trial; ROSC, return of spontaneous circulation; SADE, serious adverse device event; SAE, serious adverse event; SGA, supraglottic airway; SWAST, South Western Ambulance Service NHS Foundation Trust; UK, United Kingdom; YAS, Yorkshire Ambulance Service NHS Trust.

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Patient enrolment began in June 2015. The trial will enrol 9070 patients over two years. The results are expected to influence future resuscitation guidelines.
Trial Registration ISRCTN: 08256118.

Introduction

The United Kingdom (UK) has the highest reported incidence of out of hospital cardiac arrest (OHCA) in Europe; 123 cases per 100,000 population per annum.[1] Despite recent improvements, survival rates from cardiac arrest remain poor with approximately 7–9% of patients in the UK surviving to hospital discharge, compared with estimates of between 5% and 25% internationally.[2–5] During a cardiac arrest, the brain is exposed to a period of hypoxaemia and ischaemia, which may result in death or cognitive deficits.[6] Optimal cardiopulmonary resuscitation (CPR) and return of spontaneous circulation (ROSC) are key factors associated with avoiding or minimising neurological impairment in the survivors of OHCA,[9,10] and early effective airway management is fundamental to this.

Traditional teaching suggests that tracheal intubation is the best way to manage the airway during OHCA.[11] However, this assumption has not been well tested,[12] and pre-hospital intubation attempts by paramedics can be associated with complications such as interruptions in chest compressions, unrecognised oesophageal intubation (particularly if waveform capnography is not available), and delays in accessing definitive care.[13,14]

Supraglottic airway devices (SGAs) are an alternative to intubation. They are quicker and easier to place and may avoid the complications of tracheal intubation.[15] SGAs are used safely to manage the airway during hospital procedures.[16–18] They are also in widespread use in UK National Health Service (NHS) emergency medical services (EMS); in 2014/15 the London Ambulance Service reported 1469/1775 (83%) successful OHCA intubations, compared to 3149/3494 (90%) successful SGA placements.[5] Equipoise between the two techniques has led to recent calls for a large randomised controlled trial (RCT) of the two approaches.[19,20]

Between March 2012 and February 2013 we carried out a study (REVIVE-Airways) in a single NHS EMS provider to assess the feasibility of recruiting paramedics and patients to a study comparing two SGAs (i-gel and the Laryngeal Mask Airway Supreme) with current practice (including tracheal intubation).[21] REVIVE-airways demonstrated that the study was feasible and informed the design of AIRWAYS-2.

The Resuscitation Council (UK) 2015 guidelines state that the optimal airway technique for cardiac arrest is still unknown, and is likely to depend on the skills of the operator, the anticipated pre-hospital time and patient-dependent factors.[22] Evidence-based interventions to improve OHCA survival are still urgently required. The AIRWAYS-2 trial has the potential to answer important questions about initial advanced airway management in OHCA, examining both survival rates and the quality of that survival.

Methods and analysis

Aims and objectives

The aim of AIRWAYS-2 is to determine whether the i-gel (Intersurgical; Wokingham, UK), a second-generation SGA, is superior to tracheal intubation when used by an AIRWAYS-2 study paramedic in non-traumatic OHCA in adults, in terms of both clinical and cost effectiveness.

Specific objectives are to estimate:

1. The difference in the primary outcome of the modified Rankin Scale (mRS) at hospital discharge (or 30 days post OHCA if the patient is still in hospital) between groups of patients managed with either the i-gel or tracheal intubation as their initial advanced airway management strategy following OHCA.
2. Differences in secondary outcome measures relating to airway management, hospital stay and recovery at 3 and 6 months between groups of patients managed with either the i-gel or tracheal intubation.
3. The cost effectiveness of the i-gel compared to tracheal intubation, including estimation of major in-hospital resource use (e.g. length of stay in intensive and high dependency care), and associated costs in each group.

Design

AIRWAYS-2 is an open parallel two-group multi-centre cluster RCT. The trial schema is shown in Fig. 1. Paramedics rather than patients are randomised to one of the treatment groups and all enrolled patients should be treated according to the enrolling paramedic's allocation.

Setting

The trial involves collaboration between four UK NHS EMS providers (South Western Ambulance Service NHS Foundation Trust (SWAST), East of England Ambulance Service NHS Trust (EEAST), East Midlands Ambulance Service NHS Trust (EMAS), Yorkshire Ambulance Service NHS Trust (YAS)) and the 95 NHS hospitals served by the participating EMS providers.

Paramedic population

Paramedics are eligible if they are employed by one of the four participating EMS providers, undertake general operational duties, and can therefore be despatched to attend an OHCA as the first or second paramedic to arrive at the patient's side. They must be registered with the Health and Care Professions Council and be qualified to practice tracheal intubation in their current clinical role.

Randomisation

In AIRWAYS-2, paramedics working within SWAST, EMAS, EEAST or YAS who consent to participate in the trial are randomly allocated in a 1:1 ratio to one of the two groups: i-gel or intubation (i.e. each paramedic is a randomised cluster).

Randomisation is stratified by EMS provider, years of paramedic experience (greater than or equal to 5 years full-time operational experience versus less than 5 years full-time operational experience) and urban/rural location of the base ambulance station (defined as greater than or equal to 5 miles versus less than 5 miles from the nearest hospital with an emergency department that receives cardiac arrest patients).

Randomisation is performed using a secure computer system developed by the Bristol Clinical Trials and Evaluation Unit (CTEU), with allocation concealment that cannot be changed once allocated.