<Insert trust logo>

PARAMEDIC PARTICIPATION INFORMATION LEAFLET

<Insert name ambulance trust>

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

Research Team Contact details:

Principal Investigator
Professor Jonathan Benger
Academic Department of Emergency Care
University Hospitals Bristol NHS Foundation Trust
Emergency Department
Bristol Royal Infirmary
Bristol, BS2 8HW

Tel: 0117 3421498
Email: jonathan.benger@uwe.ac.uk

Trial Manager
Jodi Taylor
Clinical Trials and Evaluation Unit
Bristol Heart Institute
Level 7 Queens Building
Bristol Royal Infirmary
Marlborough Street
Bristol BS2 8HW

Tel: 0117 342 2987
Email: airways-2@bristol.ac.uk

Local Research Paramedic
<Insert Name of local research paramedic>
<Insert address of research paramedic>

Tel: <Insert number>
Email:<insert email>

1. INTRODUCTION

You are being invited to take part in a research study. Before you decide whether to take part or not, you need to understand why the research is being done, and what it would involve for you. Taking part in research is voluntary; it is up to you to decide to join the study. You are free to withdraw at any time, and if you choose not to take part or to withdraw from the research, you do not have to give any reason for your decision.

Please take time to read the following information carefully. If anything is not clear or you would like more information, please do not hesitate to contact your local research paramedic who is employed by your ambulance trust (contact details can be found on page 1).

The research paramedic will be more than happy to go through the information leaflet with you, explain the study in more detail, and answer any questions you may have.

2. WHAT IS THE PURPOSE OF THE STUDY?

Cardiac arrest is one of the most extreme medical emergencies. Health outcomes are poor; 90% of patients die at the scene or before discharge 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 of a return of spontaneous circulation (ROSC).

Ensuring a clear and effective 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 paramedics to manage the patient's airway during an out of hospital cardiac arrest (OHCA). Historically tracheal intubation has been considered the best method. However, tracheal intubation can cause significant complications as well as interruptions in chest compressions.

National recommendations suggest that a newer device, the supraglottic airway device (SAD), may be better than tracheal intubation. SADs are already used during routine anaesthesia in hospital; in emergency care, they are quicker to insert and cause less interruption to chest compressions. However, a SAD may not stay in place as securely as a tracheal tube and, if a patient vomits, stomach contents may get into their lungs.

There is real uncertainty amongst paramedics and experts in the field about the best method to ensure a clear airway during the early stages of OHCA. We are therefore undertaking a large research study to determine whether intubation or the best available SAD (the i-gel) gives the best chance of recovery following OHCA.

This study is a randomised controlled trial (RCT) being carried out in four English NHS ambulance services. It will recruit adult OHCA patients who have suffered a cardiac arrest that is not due to trauma. Paramedics who agree to take part will be divided into two groups and given structured education on CPR and rescue breathing. One group will be required to use the i-gel and the other intubation as the first method of rescue breathing in all cases of OHCA that they attend during the study.

3. WHY HAVE I BEEN INVITED?

All paramedics working in operational duties for: East of England Ambulance Service NHS Trust; East Midlands Ambulance Service NHS Trust; South Western Ambulance Service NHS

Foundation Trust and Yorkshire Ambulance Service NHS Trust are being invited to take part. We are aiming to recruit 1,300 paramedics in total.

4. WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you return the expression of interest form the research team will contact you to invite you to attend a trial specific training. This session is structured and will last approximately 2 hours.

Initial training- part 1

The first part of the training session will include a presentation that reviews current resuscitation guidelines and the options available for airway management. It will consist of training on study procedures, data collection and we will explain the purpose of the trial, equipoise and the need to follow trial protocols.

At this stage you will be given the opportunity to ask questions and then we will invite you to complete a consent form. If you no longer wish to participate in the study you will be free to leave the training session.

Once you have consented to take part in the study you will be randomly allocated to one of the two study arms and asked to use either the i-gel supraglottic airway device or tracheal intubation as your initial approach to airway management at every adult non-traumatic cardiac arrest that you attend over the following 24 months. In both study arms a short period of bag-mask ventilation may be used prior to your allocated device.

Note that the trial only specifies your initial airway management technique; if this proves unsuccessful subsequent airway management will follow recognised algorithms, applied using your clinical judgement in the patient's best interests. Once the research has finished you will return to your usual practice, and additional training will be provided at the end of the study so you do not de-skill as a result of taking part.

Initial training– part2

The second part of your initial training session will be tailored to the trial group to which you are randomised. You will complete technical training on either the i-gel or tracheal intubation.

The training will be provided in accordance with manufacturer's guidelines and you will be allowed as much time as you need to repeatedly practice on the manikin until you are confident with the technique. You will then complete a brief verbal and practical assessment.

The training session will close with a reminder of the study's purpose and protocol, familiarisation with the data collection form and an opportunity to ask questions and review.

If you are randomised to the i-gel arm, you will be issued with a personal supply of the device, and will be required to account for each use. Additional supplies of the i-gel will be issued by the Research Paramedic in exchange for completed data collection forms

5. WHAT WILL I HAVE TO DO?

You will not be able to recruit patients until you have attended the training described above, but once you have completed training (and from the start date of the study 01/06/2015) you will be

required to use your allocated method of airway management for every adult non-traumatic cardiac arrest that you attend during the 24 month study period unless you are the third or later paramedic to arrive, or another paramedic participating in the trial arrives at scene before you, in which case they will manage the airway according to their study allocation, and you will assist as you would normally.

Each time you attend a cardiac arrest you will be required to complete a Case Record Form (CRF) and return it to the study Research Paramedic in your trust (contact details below). This will take no more than a few minutes.

You will be invited to attend refresher training after 12 months and exit training at the end of the study, which will concentrate on refreshing your skills in the airway management technique that you were not allocated to use during the trial.

6. EXPENSES AND PAYMENTS

The following payments will be made to you if you decide to take part in the study in recognition of your time spent training:

A) You will be entitled to receive overtime payments for the time you spend at study training sessions
B) You will be able to claim reasonable travel expenses for attending the training.

7. WHAT ALTERNATIVES ARE THERE TO TAKING PART IN THE STUDY?

If you choose not to take part you will continue to manage cardiac arrests in the usual way, and there will be no penalty or disadvantage to you.

8. WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

There are no perceived disadvantages or risks to you from taking part.

9. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

If you decide to take part you will receive additional training, and a chance to participate in this research study. Ultimately, future cardiac arrest patients may benefit from improved airway management partly as a result of the information that you collect during this research study.

10. WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

At the end of the study you will be invited to attend additional “exit” training to update your airway skills before returning to your usual practice. If you are in the i-gel arm, you will need to return any unused devices to the Study Research Paramedic

11. WHAT IF THERE IS A PROBLEM?

If you have any concerns or questions about this study, please contact the research team listed at the front of this leaflet. Please feel free to ask any further questions before deciding to take part in the trial, or at any time during the study.

12. WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

All study data will be anonymised so you cannot be identified as an individual in any report, presentation, research paper or other study output. Your clinical skills will not be compared to other paramedics. The findings from the study will be reported in medical journals or presented at meetings but your identity will not be disclosed. During the course of the study we will ask you if you would like to receive a summary of the results by post after the research has finished.

13. WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes we get new information about the treatment being studied. If this happens, the research team will tell you and decide whether the study should continue.

14. WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You are free to withdraw from the study at any time, without giving a reason. If you withdraw, you will return to your usual practice and will not be penalised in any way. You will not be asked to complete any more data collection forms, but those already submitted will still be included in the study results.

15. WHO IS ORGANISING AND FUNDING THE RESEARCH?

The research is funded by the National Institute for Health Research. South Western Ambulance Service NHS Foundation Trust has overall responsibility for the conduct of the study. The research is being organised and run on their behalf by the Clinical Trials and Evaluation Unit, University of Bristol. Participation in this study is supported by the College of Paramedics.

16. WHO HAS LOOKED AT THE STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by Cambridge Research Ethics Committee.

17. FURTHER INFORMATION

You can obtain **general advice on out of hospital cardiac arrest** and its treatment from the British Heart Foundation (www.bhf.org.uk). Tel: 0300 330 3311

You can obtain **general information on clinical research** from the UK Clinical Research Collaboration (UKCRC) who produce a booklet called "Understanding Clinical Trials". This provides in-depth information on the design and conduct of clinical trials and aims to answer the questions of those considering taking part.

Electronic copies can be downloaded from the UKCRC website:
www.ukcrc.org/publications/informationbooklets.aspx.

Printed copies can be requested by emailing: info@ukcrn.org.uk
Or by contacting: UK Clinical Research Collaboration,
20 Park Crescent,
London, W1B 1AL
Tel: 020 7670 5452.

Thank you for taking the time to read this leaflet.