PATIENT PARTICIPANT INFORMATION LEAFLET

Airway Management in cardiac arrest patients (Airways-2)

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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 whether you 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. Nobody will be upset, and the care you receive will not be affected if you decide not to take part.

Please take time to read the following information carefully. **One of our team will go through the information leaflet with you, explain the study in more detail, and answer any questions you have**. If anything is not clear or you would like more information, do not hesitate to ask a member of the local research team (see contact details on page 1). Talk to others about the study if you wish, such as friends or relatives, and take time to decide. If you would like to take part, you will be asked to confirm by signing a separate consent form and will be given a copy of this for your records.

2. WHAT IS THE PURPOSE OF THE STUDY?

Cardiac arrest occurs when the heartbeat and breathing stop suddenly, and is one of the most extreme medical emergencies. Health outcomes are usually 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 a cardiac arrest (out of hospital cardiac arrest: OHCA). Placing a breathing tube in the windpipe (intubation) has been considered the best method. However, attempting to place the breathing tube can cause complications as well as interruptions in chest compressions.

National recommendations suggest the possibility of using a newer method: insertion of a supraglottic airway device; a tube that sits on top of the voice box. Supraglottic airway devices 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 supraglottic airway device may not stay in place as securely as a breathing 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 tracheal intubation or the best available supraglottic airway device (called the i-gel) gives the best chance of recovery following OHCA.

This study is taking place in four English NHS ambulance services. It is recruiting adult OHCA patients like yourself, who have suffered a cardiac arrest that is not due to injury. Paramedics who agreed to take part in the study were divided into two groups; one group uses the newer supraglottic airway device to treat all the patients they attend with cardiac arrest during the study, while the second group of paramedics uses the intubation method to treat all their patients. Prior to the start of the trial paramedics were given extra education on CPR and rescue breathing.

3. WHY HAVE I BEEN INVITED?

The ambulance service that treated your cardiac arrest is taking part in this study. We would like your permission to collect some additional information from you and your hospital notes about your quality of life around the time you leave hospital, and at approximately 3 and 6 months after your cardiac arrest happened. We are aiming to recruit 9,000 patients in total, with 3 and 6 month data being collected in patients that have survived and consent to continue in the study.

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

You have already received treatment for your cardiac arrest, and as part of your treatment either the newer supraglottic airway device or the intubation method was used to manage your airway.

As you have already taken part in the study, we are now asking you to complete a consent form to indicate whether or not you would like to continue to be involved in the follow up phase of this study. Continuing in the study will not involve any additional or different treatment but it will allow us to collect important information about your recovery, and help us to determine which airway management technique should be used by paramedics attending a cardiac arrest.

If you would like to take part in the study you can consent to either **active** follow up (option A on the consent form) or **passive** follow up (option B on the consent form) - See section 5 for a description of the two follow up methods.

If you **do not wish to take any further part** in the study, we will ask you to select option C on the consent form.

By selecting option C - no further information will be collected about your cardiac arrest, but the information about your cardiac arrest and treatment up to this point will still be included in the analysis of the study. It will be anonymised, so you cannot be personally identified. If you wish to take this option we will not contact you again.

5. WHAT WILL I HAVE TO DO?

ACTIVE FOLLOW UP- Option A on consent form

If you consent to active follow up we will continue to collect information about you from your records, for example: outpatient appointments, GP visits, A&E attendances, and any inpatient treatments. In addition, we would like to invite you to complete some questionnaires 3 months and 6 months after your cardiac arrest. These questionnaires will ask about your ongoing health and wellbeing, and will take no more than one hour to complete.

They can be administered over the telephone, by e-mail or by post or completed online. If you wish, it can also be administered in person at your home, or during a visit to a hospital clinic. This will give us important extra information about your recovery and allow us to plan future research in this area.

PASSIVE FOLLOW UP- Option B on consent form

If you consent to passive follow up we will continue to collect information about you from your records, for example: outpatient appointments, GP visits, A&E attendances, and any inpatient treatments but you will not have to complete any questionnaires.

6. WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

You have already received treatment for your cardiac arrest. There are no anticipated disadvantages or risks to you from taking part. Continuing to take part in the study will not benefit you directly, but the information we get from this study will help improve the treatment of people who have an out of hospital cardiac arrest in the future.

7. WHEN DOES THE RESEARCH STUDY STOP?

Once we have collected follow-up data from you at 3 and 6 months your participation in the study will be complete.

You will not incur any expenses as a result of being in the study, and you will not be paid for taking part.

8. WHAT IF THERE IS A PROBLEM?

If you have any concerns or questions about this study, please contact the research team listed at the start 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.

If you have concerns about the way you have been approached or treated during the course of the study, you may wish to contact the Patient Advice and Liaison Service (PALS) on:

<Insert ambulance trust PAL details>

If you wish to make a formal complaint, please write to:

<Insert ambulance trust PAL details>

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

Your medical notes will need to be seen by authorised members of the hospital research team so they can collect information needed for this research study. With your consent, your GP will also be informed that you are taking part in the research study. Your GP may be asked to provide information from your records which is required for the research.

Occasionally, other members of NHS staff or research staff may need to check your medical records. This will be done by NHS staff or by researchers who are bound by the same rules of confidentiality as all NHS staff. Regulatory authorities and the hospital trust overseeing the research may also need to look at your notes but the confidentiality of your medical records will be respected at all times.

All information which is collected about you during the course of this research will be kept strictly confidential. The information that will be collected includes personal information such as your name, address and NHS number. This will allow us to keep in touch with you during your participation in this research, enabling us to collect information about your quality of life.

Electronic information collected by the hospital where you were treated may be securely transferred within the NHS to the University Hospitals Bristol NHS Foundation Trust. The information collected will be stored in a secure database held at the co-ordinating centre (CTEU, Bristol) and will only be accessed by authorised members of staff involved in the research. This includes the hospital research team and staff at the coordinating centre who are managing the research and will be responsible for aspects of your follow-up such as sending you questionnaires.
The findings from the study may 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. Under no circumstances will you be identified in any way in any report arising from the study.

10. 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, we will use the information that we have already collected about you unless you specifically request us not to.

11. 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 conduct of the study. The research is being organised and run on their behalf by the Clinical Trials and Evaluation Unit, University of Bristol.

12. 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 been given a favourable opinion by South-Central Oxford C Research Ethics Committee.

13. 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:
http://www.ukcrc.org/patients-and-public/public-awareness-of-clinical-research/information-resources-on-clinical-research/

Printed copies can be requested by emailing: crncc.info@nihr.ac.uk

Or contacting:
UK Clinical Research Collaboration,
C/O Medical Research Council
One Kemble Street
London WC2B 4TS
Tel: 020 7395 2271

Thank you for taking the time to read this leaflet.