

## **Information about the Research**

### **PARAMEDIC-2: The Adrenaline Trial**

You have been given this leaflet to read and consider because you were taken to hospital after suffering a cardiac arrest (your heart stopped beating). The Ambulance Service that treated you is taking part in a clinical trial, called PARAMEDIC-2: The Adrenaline Trial.

This information sheet explains the trial and what it means for you. One of our team will go through the information sheet with you and answer any questions you have. We'd suggest this should take about 20 minutes. Talk to others about the study if you wish and don't be afraid to ask us questions.

#### **Information about the research**

A cardiac arrest occurs when the heart suddenly stops beating, and is one of the most severe medical emergencies. The immediate treatment for a cardiac arrest is cardiopulmonary resuscitation (CPR): this is a combination of rescue breathing and chest compressions. Prompt and effective CPR is essential to prevent damage to vital organs, and increases the chance of survival. In addition to CPR other advanced treatments are given like defibrillation (electrical shocks) and oxygen.

If initial treatments are not effective at restarting the heart, some people are given a drug called adrenaline. Although adrenaline has been used to treat cardiac arrest for a number of years, no one is really sure about whether it is safe and effective for improving long-term survival and helping the brain to recover.

When doctors, nurses and paramedics do not know whether a treatment is effective or not it is common to undertake a research study. Research studies of this type involve putting people into two groups where one group receive the active drug (in this case adrenaline) and the other group a dummy drug (known as a placebo). The results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). The study is referred to as a "double blind trial", as neither the patient nor the paramedic / nurse/ doctor will know in which treatment group someone was in.

#### **What is the purpose of the trial?**

The aim of this trial is to work out how safe and effective adrenaline is as a treatment for cardiac arrest.

**Why have I been chosen?**

You will have received either adrenaline or placebo as part of your treatment. When your heart stopped you lost consciousness immediately. As a result, the Paramedics were unable to discuss with you your views about participation in the trial at the time of your cardiac arrest. It was also not possible for the Paramedics to speak to those close to you to obtain consent as this may have delayed your emergency treatment. In this situation the Ambulance Service are authorised to use a waiver of consent at the time of the emergency.

We are now asking your permission to continue in the next phase of the research study.

**What will happen to me if I agree to continue to take part?**

You received the treatment that forms part of this study at the time of your cardiac arrest and data about your cardiac arrest was collected. There are no further trial related treatments required.

We will follow how your recovery progresses over the next 12 months. We propose to do this in two ways. Firstly we will ask the doctors / nurses / paramedics to look at your NHS records to let us know how you are getting on. This will include information about how long you spent in hospital, what treatments you required and how well you recovered. Some of this information will be obtained from the Health and Social Care Information Centre who are part of the NHS and look after health and care information.

We will invite you to participate in answering short questions around 3 and 6 months after you sustained the cardiac arrest. This can be done over the telephone, by post or in-person with a member of the research team. We estimate it will take approximately one hour to answer the questions.

**Do I have to take part?**

You do not have to agree to take part. If, as is your right, you choose not to participate in any aspect of the study any further, it will not affect the treatment or care that you receive in anyway.

You can indicate if you would like to take part in each aspect of the follow up on the consent form which will need to be signed and dated. A copy is enclosed for your information.

**What are the possible risks and benefits of taking part?**

The risks from you continuing in the trial are small. Although most people remember very little about their cardiac arrest, receiving a questionnaire or a visit from a researcher could be

upsetting. Our trained research staff can talk to you about any such feelings and can offer to put you in contact with professional services if required.

Continuing to be part of the trial will require a modest time commitment to complete the questionnaires. However, the information we collect from you will help us know how best to treat people with this condition in the future and answer questions on how safe and effective adrenaline is as a treatment for cardiac arrest.

### **What if something goes wrong?**

It is extremely unlikely that anything will go wrong as a result of taking part in this trial, because treatment for your cardiac arrest has already finished. However, if you feel that you have been harmed during your treatment due to someone's negligence, then you may have grounds for a legal action against the relevant NHS organisation, but you may have to pay your legal costs.

### **What happens if I have any questions, concerns or complaints about the trial?**

If you have any questions about the trial or concerns about the way it has been carried out, you should contact the University of Warwick Deputy Registrar, Ms Jo Horsburgh (contact details below). If you are unhappy about any aspect of your treatment and wish to complain, you can do this through the NHS Complaints Procedure. You can contact the local ambulance service Patient Advice Liaison Service (PALS) or local Clinical Commissioning Group (previously known as Primary Care Trusts). For more information on the NHS complaints procedure or to find your local contact go to:

<http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/>.

### **Will my participation in the trial be kept confidential?**

All information that is collected about you during the trial will be kept strictly confidential, and will only be seen by authorised staff involved in the research and people from regulatory authorities who ensure that research studies are carried out correctly. All of them will have a duty of confidentiality to you as a research participant. All information will be handled securely, in line with relevant laws such as the Data Protection Act.

Any personal information about you will only be used for this research trial. Anonymised data may be used for future research.

You have the right to see your personal health information relating to the research trial, but you will not be able to review some parts of the information until after the trial has finished.

### **What happens if I don't want to carry on with the trial?**

You are free to stop participating in the trial at any time you wish without giving a reason and without affecting your rights. If you decide to stop participating, we will not send you any further questionnaires. We will continue to collect information remotely about your overall health unless you write to us specifically to request that we do not.

### **What will happen to the results of the research trial?**

The trial is expected to take around four years. We will share the results of the trial with other healthcare professionals and will publish the results of the trial in medical journals. When any information from the trial is published it will not contain personal information, and it will not be possible to identify you.

We will endeavour to make sure the results of the trial are shared widely. If you would like a copy of the published results, please contact the Trial Team (contact details below).

### **Who is organising and funding the trial?**

The trial is organised by a group of doctors, paramedics and scientists led by Professor Gavin Perkins, who works at the Heart of England NHS Foundation Trust and the University of Warwick. Several Ambulance Services are taking part in this trial across the UK.

The costs of the trial are being met by the NHS and the National Institute for Health Research (Health Technology Assessment Programme).

### **Who has reviewed the trial?**

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This trial was reviewed and given a favourable opinion by the South Central Oxford C Research Ethics Committee on 21<sup>st</sup> May 2014. The Trial has also been reviewed by the Medicines and Healthcare Products Regulatory Agency (MHRA) and National Institute for Healthcare Research (NIHR) Health Technology Assessment Board.

### **What happens next?**

You do not have to do anything now. A member of the Research Team will contact you again to discuss this further.

### **Who do I contact for more information?**

- 1) PI FOR LOCAL SITE NAME, [email].
- 2) RESEARCH PARAMEDIC NAME, [email]. Tel: [mobile].
- 3) Trial Team at the University of Warwick: Email: [paramedictrial@warwick.ac.uk](mailto:paramedictrial@warwick.ac.uk) Tel: 024 761 51164

**Contact details for concerns or complaints about the Research, Staff, Conduct:**

Ms Jo Horsburgh, Deputy Registrar, University of Warwick, Research Support Services,  
University House, Kirby Corner Road, Coventry, CV4 8UW, Email: [n.lynch@warwick.ac.uk](mailto:n.lynch@warwick.ac.uk),  
Tel: 024 7652 2785

**Thank you for reading this information sheet**