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ARREST

A randomised trial of expedited transfer to a cardiac arrest centre for non-ST elevation out-of-hospital cardiac arrest

A randomised trial of expedited transfer to a cardiac arrest centre for non-ST elevation out-of-hospital cardiac arrest. (ARREST)

PERSONAL CONSULTEE INFORMATION SHEET

Funded by the British Heart Foundation

You have been given this leaflet to read and consider because your relative/friend/partner was taken to hospital after suffering a cardiac arrest. The London Ambulance Service, who treated your relative/friend/partner initially, is taking part in a study called the ARREST and entered your relative/friend/partner into this research study.

We feel your relative/friend/partner is currently unable to decide for themselves whether to continue their participation in this research.

To help decide if they should remain in the study, we would like to ask your opinion whether they would want to be involved. We ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

Before you decide whether or not your relative/friend/partner should continue in the study, it is important for you to understand why the research is being done. We will ask you to read the following information which explains the trial. Please take time to read the information carefully and discuss it with others if you wish, and don't be afraid to ask us questions if there is anything that is not clear or if you would like more information.

If you decide that your relative/friend/partner would have no objection to taking part, we will ask you to read and sign the consultee declaration form. We will give you a copy of this form and the Personal Consultee Information Sheet to keep. During the trial please let us know if you have any concerns or you think your relative/friend/partner should be withdrawn.

If you decide that your friend/relative/partner would not wish to take part it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek independent advice.

We will understand if you do not want to take on this responsibility.

The following information is the same as would have been provided to your relative/friend/partner.

Information about the research
The ARREST study will help doctors and paramedics decide the best treatment for patients in cardiac arrest. A cardiac arrest happens when a person's heart stops pumping blood to their body. Most cardiac arrests happen because of a sudden heart attack.

Some research suggests that patients who have had a cardiac arrest may benefit if we treat them in the same way that we treat heart attack patients. We treat those who have had a heart attack in specialised hospital departments known as Heart Attack Centres. The aim of this study is to determine whether patients who have had a cardiac arrest would benefit from being taken directly to a Heart Attack Centre by the ambulance service.

Why has my relative/friend/partner been chosen?
Patients who have had a cardiac arrest are eligible for this important study. Your relative/friend/partner was entered into the study by the paramedics who attended their cardiac arrest.

What has happened to them so far in the study?
When they were entered into the study they were treated in one of two different ways. They were either transported to an emergency department, or they were transported to a Heart Attack Centre. Their medical care after this point remains unchanged. If you are unsure of which department they were taken to, you can ask one of the research team.

Patients who have had a cardiac arrest can initially be too ill to make decisions about taking part in research. A National Research Ethics Committee reviewed this study and confirmed that the trial is important enough to include patients who were unable to make a decision for themselves at the time. It may not have been possible for the paramedics to speak to those close to you to obtain consent at the time as this may have delayed their emergency treatment.

We are now asking you whether your relative/friend/partner should continue in the next phase of the research study.

What happened if my relative/friend/partner was taken to an emergency department?
They will have received the standard treatment for patients who have had a cardiac arrest. Their medical care is the same as the care they would have received if they were not in this study. Paramedics will have transported them to the closest emergency department. The senior doctor looking after them will have attempted to reverse the cause of their cardiac arrest. This may include a coronary angiogram (see below).

What happened if my relative/friend/partner was taken to a Heart Attack Centre?
They will have received the usual treatment for patients who have had a heart attack. Paramedics will have transported them as quickly as possible to a Heart Attack Centre. The medical staff will have performed a **coronary angiogram** if deemed appropriate by the receiving cardiology team (see below).

What is a coronary angiogram?
A coronary angiogram is a procedure which looks at the arteries (blood vessels) in your heart. This allows your doctor to identify narrowing in your arteries that may be restricting the flow of blood to your heart. During the procedure, a thin plastic tube called a catheter is guided to your heart through an artery. A special dye is injected through the catheter which clearly shows the arteries on an X-ray. If you have any narrowing to the arteries in your heart this is known as coronary artery disease. A variety of treatments are available for coronary artery disease. One of the most common is **coronary angioplasty**.

What is coronary angioplasty?
In coronary angioplasty a small balloon is passed through the same catheter that was used for the coronary angiogram. Once the balloon reaches the narrow section of the artery it is expanded to widen the artery. This allows blood to flow more easily. To keep the artery open, a device called a stent (a small mesh tube) is inserted. The stent is left in place to ensure the artery remains open after the balloon and catheter are removed.

What are the risks of coronary angiogram and angioplasty?
There is up to a 1 in 100 risk of complication. This includes bruising or bleeding at the site where the catheter goes in, damage to the heart muscle (heart attack), irregular or abnormal heartbeat (dysrhythmia), stroke, coronary artery bypass grafting (very rare), or death specifically related to the procedure (very rare: 1 in 1000).

How was their treatment decided?
Half of the patients in the study are taken to an emergency department and half are taken to a Heart Attack Centre. This was chosen at random by a computer rather than by a doctor or paramedic. This is called randomisation. Randomisation makes the study scientifically strong. They had a 50% (or 1 in 2) chance of being placed in either group.

What will happen to them as part of the study?
If you agree to your relative/friend/partner's continuation in the study, we will follow how their recovery progresses over the next 12 months. It is up to you to decide how we get in touch with you or your relative/friend/partner. If you would like not to be contacted you can make this choice on the consent form.

We have already collected some information about your relative/friend/partner's care up until this point and would like to keep it. It is your choice whether you are happy for us to do so.

We will record some of the data that is collected as part of their normal care during their stay in hospital. This will include information about how long they spent in hospital, what treatments they required and how well they recovered.

If you agree, you may be contacted via telephone 3 months after their admission for a short health assessment. This will not require you or them to come into the hospital.

We will access their hospital records to gather information on their health for up to one year after your admission. Neither you or they will need to be contacted for this.

Will extra blood samples be collected?
No. The blood samples that are taken as part of their normal care are all that will be taken.

Will any other tests be done?
No. The tests that they receive as part of your normal care at hospital are all they will receive.

Do I have to agree for my relative/friend/partner to take part?
You do not have to agree for them to take part.

We would like to ask your opinion whether they would want to be involved. We ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence. If, as is your right, you choose that they should not participate in any aspect of the study, it will not affect the treatment or care that they receive in any way.

If you decide that your relative/friend/partner would have no objection to taking part, we will ask you to read and sign the consultee declaration form. We will give you a copy of this form and this information sheet to keep. **.**

It is important to know that you are free to withdraw your consent for your relative/friend/partner's involvement in the study at any time. You do not need to give a reason if you decide that they should no longer be involved. If you decide that they should withdraw from the study, it will not affect the treatment or care they receive. We will continue to collect information remotely about their overall health unless you or they write to us specifically to request that we do not.

What are the possible risks and benefits of continuing to take part?
The risks from you and your relative/friend/partner continuing in the trial are small. Receiving a phone call from a researcher could be upsetting. Our trained research staff can talk to you or your relative/friend/partner about any such feelings and can offer to put you in contact with professional services if required.

Participating in this study will help us to determine the best urgent care for patients who have had a cardiac arrest.

Will their taking part in this study be kept confidential?
Yes. All the information about their participation in this study will be kept confidential. The study is being run by the Clinical Trials Unit at the London School of Hygiene and Tropical Medicine. They are responsible for analysing the data and may need to look at parts of your relative/friend/partner's medical records. They will be allocated a unique study number which will be used on data taken outside of the hospital. The Clinical Trials Unit at London School of Hygiene and Tropical Medicine may be sent a copy of their consent form to make sure it has been completed correctly.

What if relevant new information becomes available?
Sometimes during the course of a research study, new information becomes available

about the treatment that is being studied. If this happens, a member of the research team will tell you about it and discuss whether you want your relative/friend/partner to continue with the study. If the study is stopped for any other reason you will be told why.

Who has reviewed the study?
An independent Research Ethics Committee (REC) has approved this research. The study has been reviewed and approved by National Research Ethics Service (NRES) Committee London – South East.

What will happen to the results of the research study?
The results will be published in a reputable medical journal. Nothing that could link your relative/friend/partner's information to them personally will be used in any reports or publications.

Who is organising and funding the study?
The study is being run in collaboration between King's College London, Guy's and St Thomas' NHS Foundation Trust, London School of Hygiene and Tropical Medicine and the London Ambulance Service. The study is funded by a charity called the British Heart Foundation.

Who do I speak to if a problem arises?
If you wish to complain, or have any concerns about any aspect of the way you or your relative/friend/partner has been approached or treated by members of staff due to their participation in the research, the National Health Service or King's College London complaints mechanisms are available to you. Please ask a member of the research team if you would like more information on this.

In the unlikely event that your relative/friend/partner is harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor's (King's College London) or the hospital's negligence then you may be able to claim compensation. After discussing with the research staff please make the claim in writing to Professor Simon Redwood, the Chief Investigator for the research based at King's College London. The Chief Investigator will pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action, and you should consult a lawyer about this.

Professor Simon Redwood
King's College London
The Rayne Institute
4th Floor, Lambeth Wing
St Thomas' Hospital
London SE1 7EH

How to contact the researchers
The researchers conducting this study at the hospital can be contacted using the following

details:

Insert research paramedic contact details
Insert contact details of local PI, research nurses