PATIENT INFORMATION SHEET FOR PATIENTS NOT ENROLLED IN STUDY
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Sub30: A feasibility study of a pre-hospital ECMO in patients with refractory cardiac arrest.

This leaflet explains the Sub30 research study. We considered whether you should be part of this this study because you had a cardiac arrest within the area of Barts Health NHS Trust. It was not possible to discuss this with you beforehand as you were unconscious when you had a cardiac arrest.

The Sub30 study is testing whether it is possible to support patients quickly on an ECMO machine when their hearts are stopped. ECMO machines can replace the function of the heart when it is stopped and ensure enough blood and oxygen get to the brain and other vital organs in a patient.

You did not receive ECMO. This usually occurs because a patient's heart was restarted by the paramedics and doctors before the ECMO machine was needed.

We are giving you this information leaflet as we want patients to know as much as possible about their care. Please ask us if there is anything that is not clear or you do not understand, or if you would like more information.

What is the purpose of the study?

Every year, in London, the ambulance service treats over 4,000 patients who have a had a cardiac arrest (or their heart has stopped). Less than 1 in 10 patients survive to get home. Some of those who survive have severe brain damage since their brains did not receive blood and oxygen when their heart was stopped.

The ambulance service in London manages to get to a patient, on average, 7 minutes following a 999 call. The paramedics are very skilled in restarting people's hearts and often manage this in less than 10 minutes. However, sometimes it can take much longer or not be possible. The risks of a patient dying or suffering brain damage increase the longer it takes to restart the heart, particularly if after about 20-30 minutes. An extracorporeal membrane oxygenation (ECMO) machine may reduce these risks by pumping a patient's blood through an artificial lung and to their vital body organs – temporarily replacing the function of the heart and lungs. The ECMO is used in normal care to support patients after a cardiac arrest once a patient reaches the hospital, but in this study we want to see if the ECMO can be used very soon after the cardiac arrest is reported via the 999 call.

In this study, we want the ECMO team and machine to travel immediately to where the patient collapses rather than wait for the patient to be moved to a hospital. We think that the ECMO will be started faster and that this will be better for patient survival.

The ECMO team consists of three senior doctors and a paramedic. They attend patients who have collapsed and start ECMO if standard techniques fail to restart the heart in 20 minutes. They are aiming to have the ECMO machine started within 30 minutes of the 999 call. The team have achieved this in training with 'pretend' patients. The current study is assessing whether it is possible to do this in six patients in real-life.

What happened to you?

Whilst you were collapsed, doctors inserted two very fine wires into the blood vessels in your groin. These wires would have been used to help insert the plastic tubes that connect an ECMO machine to a patient. Since you did not receive ECMO we used these wires to put small plastic tubes into the vessels to measure your blood pressure and allow us to administer medications. These plastic tubes would normally have been inserted when you reached the hospital.

Thereafter your care was normal for patient who has had a cardiac arrest. You were moved to the Heart Attack Centre at St Bartholomew's Hospital where you were assessed by a heart specialist. Most patients then have a X-ray test called a coronary angiogram. This test looks at the blood supply to the heart. Blockages in the vessels that feed the heart are often the reason for patients suffering a cardiac arrest. Blockages can usually be treated during the coronary angiogram with a stent. You will have then been moved to the Intensive Care Unit at St Bartholomew's.

We are monitoring patients for seven days to check that they did not have any problems related to the insertion of the wires.

What happens now?

Your care will continue as usual for patients following a cardiac arrest.

Who is organising and funding the research?

Barts Health NHS Trust is the sponsor of the study and is responsible for ensuring all aspects of the study are carried out to the highest standard.

This study is funded by Barts Charity and London's Air Ambulance. The study will be overseen and managed by the Cardiovascular Clinical Trials Unit (CVCTU), based at the William Harvey Research Institute. None of the staff involved in the study will receive payment specific to their involvement in this research.

Who has reviewed the study?

All research in the NHS is checked by an independent group of people to protect your safety, rights, well-being and dignity. This study has been given favourable opinions by the Barts Heart Centre Research Committee, International ECMO research Network (ECMONet), Barts Health NHS Trust (the sponsor) and London Harrow NHS Research Ethics Committee.

What if there is a problem?

If you are worried about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. They are Dr Simon Finney or Dr Ben Singer. They can be contacted via the Intensive Care Unit at St Bartholomew's Hospital (Direct dial telephone number 020 3465 6911 or via email sub30study.bartshealth@nhs.net).

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. The Patient Advisory and Liaison Services (PALS) will tell you how to do this. Their telephone number is 020 3465 5919. PALS can also be contacted via email at sbhpals.bartshealth@nhs.net

If you are harmed and this is due to someone's negligence then you may have grounds for a legal action against Barts Health NHS Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

How will we use information about you?

We will need to use information from your medical records for this research project. This information will include your date of birth and initials. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available at www.hra.nhs.uk/media/documents/My_data_and_research.pdf
- by asking one of the research team
- by sending an email to dpo.bartshealth@nhs.net
- by ringing us on 020 7480 4892