PATIENT INFORMATION SHEET
Version 2.1, 20 September 2020

Sub30: A feasibility study of a pre-hospital ECMO in patients with refractory cardiac arrest.

This leaflet explains the Sub30 research study. You have been included as part of this study because you had a cardiac arrest within the area of Barts Health NHS Trust. It was not possible to ask for your permission beforehand as you were unconscious when you had a cardiac arrest. We would like to invite you to continue participating in the study. This is voluntary. If you decide you would rather not continue to take part, then it will not affect the standard of care you will receive.

Please take time to read the following information. 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.

Why have I been included in the study?

You were included in this study as when you collapsed the paramedics and ambulance service were not able to restart your heart within 20 minutes. The ECMO team also attended the cardiac arrest and thought that ECMO would protect your brain and vital

organs until your heart could be restarted. They could not ask your permission as you were unconscious. There was insufficient time to discuss the study with your family or friends.

Do I have to continue taking part in the study?

No. It is up to you to decide whether or continue to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form to show you have agreed to take part. You may choose not to participate in this study or you may leave the study at any time without giving a reason. This would not affect the standard of care that you receive.

If you ask to leave the study, we will not collect any more data about you. We will keep the information about you that we have already obtained. The lawful basis for keeping these data is that they were collected in approved medical research which is considered a task carried out in the public interest. More details about Barts Health looks after your information and maintains your privacy are below in the Section about Data Transparency.

What happens to patients who are part of the study?

When you were collapsed, ECMO was started by inserting plastic tubes in the blood vessels in your groin. These tubes connected you to the ECMO machine and allowed blood to pass from your veins to the machine and back to your arteries.

You were then moved to the Heart Attack Centre at St Bartholomew's Hospital where you were assessed by a heart specialist and further attempts were made to restart your heart. 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 where the ECMO was continued whilst your heart was given time to recover. During this period most patients remain unconscious as we give them sedative medicines to keep them comfortable. Once your heart had regained sufficient strength, the ECMO machines was stopped. After this the sedative medicines are stopped and patients start to wake up.

We would like to continue monitoring you to see how well you recover. We will use two methods of assessment. The EQ5D is a questionnaire that takes less than 5 minutes to fill in and is a an estimate of your quality of life, It is used a lot in research studies. A physiotherapist or occupational therapist will also assess your physical abilities using a measurement called the Functional Independence Measure (FIM). This takes 30 to 45 minutes to complete. We would like to do them just before you are discharged from the hospital and three months later. They will be explained in much more detail at the time.

We will take routine blood samples that are part of standard care. We will also use these blood samples to check for markers of brain injury, which may help us to obtain information on the potential benefits of ECMO for future patients. We will also request that blood samples can be frozen and stored for future analyses.

What are the possible disadvantages and risks of taking part?

The plastic tubes that are placed in the blood vessels of the groin are sufficiently large that they block the blood flow to a patient's leg. Sometimes the reduced blood flow can result in

severe damage to the leg which may lead to part of the leg being amputated. The nurses check for this complication carefully using a special monitor and checking that they can feel the pulses in the leg every hour. If we see early signs of a poor blood flow to a leg we often move the plastic tube to another blood vessel to avoid the problem becoming more severe.

Whilst on ECMO a patient is given a medicine called heparin to stop the blood clotting in the ECMO circuit. Heparin 'thins' the blood and increases the risks of a patient bleeding. If bleeding is seen around the plastic tubes that were inserted into the blood vessels then this can often be repaired by a minor surgical procedure. If the bleeding is into the brain then this can be catastrophic and the patient may die. However, these risks are much less than the risk of brain damage and death due to the cardiac arrest.

Some patients who would have died when their heart stopped but were kept alive with ECMO, may go on to survive but with brain damage. This brain damage will have occurred whilst the heart was stopped. We think that this will be limited by starting ECMO as quickly as possible.

Are there any benefits to me if I participate in the study?

If you participate in the study you may be more likely to survive your cardiac arrest or you may have less damage to your brain or other vital organs caused by the cardiac arrest.

What happens when the research study stops?

At the end of the research, your care will continue as usual.

What if I change my mind?

We understand that people change their mind. You can change your mind at any time during the study. You do not have to give us a reason for doing this. If you do not want to remain in the study then we will treat you exactly as we treat all our patients. It will not affect the quality of care you will receive.

What will happen to me if I do not take part?

You will be treated exactly the same as all of our patients at St Bartholomew's Hospital

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. Their contact details are at the end of this sheet. 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.

Will my taking part in the study be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. Any personal data will be stored in a secure and restricted access office at St Bartholomew's Hospital. Most forms and computer files will only contain a unique study code number that will not identify you. All the data in this study will be archived and then destroyed twenty years after the study has finished.

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

What will happen to the results of the research study?

At the end of the study all the research results are gathered together and analysed. We plan to publish the results of this study in a medical journal. It will not be possible to identify you from our report.

We will also invite you to a "coffee and cake" event at St Bartholomew's where we will present the results of the study to all participants and interested parties.

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 groups 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.

Contact for Further Information

If you would like more information about the study please contact 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

Email: sub30study.bartshealth@nhs.net

If you would like to talk to someone independent of the study about being involved in this research then you can contact the Patient Advisory and Liaison Services (PALS) at St Bartholomew's Hospital. Their telephone number is 020 3465 5919 and their email address is sbhpals.bartshealth@nhs.net

Thank you for taking the time to read this patient information sheet.

If you decide to continue to take part in this Sub30 Study, we will ask you to sign a consent form. You will be given a copy of the signed consent form and patient information sheet for you to keep.