ERIC-PPCI

Effect of Remote Ischaemic Conditioning on clinical outcomes in ST segment elevation myocardial infarction patients undergoing Primary Percutaneous Coronary Intervention

PATIENT INFORMATION SHEET

Funded by the British Heart Foundation

You have been invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask questions if there is anything that is not clear or if you would like more information.

Why was I approached?

You were approached to take part in this study because you were admitted to hospital with a heart attack. This was treated using a procedure called an angioplasty, which is the standard treatment for this condition. This is a procedure to open up a blocked heart artery. Your doctor will have talked through the details of the angioplasty with you.

When you were admitted to hospital, a doctor or nurse spoke to you briefly about this study and we are now asking you to consider if you are happy to carry on taking part.

What is the purpose of the study?

We are interested in finding new ways to reduce the damage caused by a heart attack. In this study, we wish to determine if the simple technique of inflating and deflating a blood pressure cuff on the arm can help reduce the damage to your heart and help your recovery. This process is called remote ischaemic conditioning **(or RIC for short)**.

Why is this study being done?

During a heart attack, damage can be caused to your heart muscle. For patients who present with a heart attack angioplasty is the most effective treatment for limiting the amount of damage caused to your heart. However, some people think that using RIC may also help reduce the damage to your heart and improve your recovery when done alongside the normal treatment of angioplasty.

The angioplasty is part of routine care and would have been carried out regardless of taking part in this study.

How might inflating a blood pressure cuff on the arm help the heart?

We, and others, have shown that reducing the blood flow to the arm for a short period of time can potentially protect the heart, lungs, and kidney from injury caused by an interruption of the blood supply. The temporary stoppage of blood to the arm activates a protective response that makes internal organs more resistant to the harmful effects of low blood flow. This is called **RIC**. There have already been several small studies looking at using the RIC procedure in patients who have had a heart attack. We now want to perform a large study of 2800 patients throughout the United Kingdom, which will help to establish whether this technique will be of benefit to patients in the long term.

Do I have to take part?

No. It is up to you to decide whether you continue to take part or not.

You should take as much time as you need to consider whether you would still like to participate. You should ask questions if anything is not clear to you.

You are free to withdraw at any time and without giving a reason. A decision to withdraw will not affect the standard of care you receive. If you decide to withdraw then please let us know if you are happy for us to use the information that has been collected on you so far. You may decide to withdraw entirely and not allow us to use any information already collected. We will use any data collected up to withdrawal, unless you ask us not to.

What will happen to me as part of the study?

You will be followed up as part of the study for one year.

Patients who are admitted with a heart attack are eligible to be included in the study. The study will recruit 2800 patients from different hospitals in the United Kingdom.

The study treatment was started before your angioplasty procedure and you will now receive the normal standard of care during the rest of your hospital admission. Taking part in the study did not delay the start of your angioplasty.

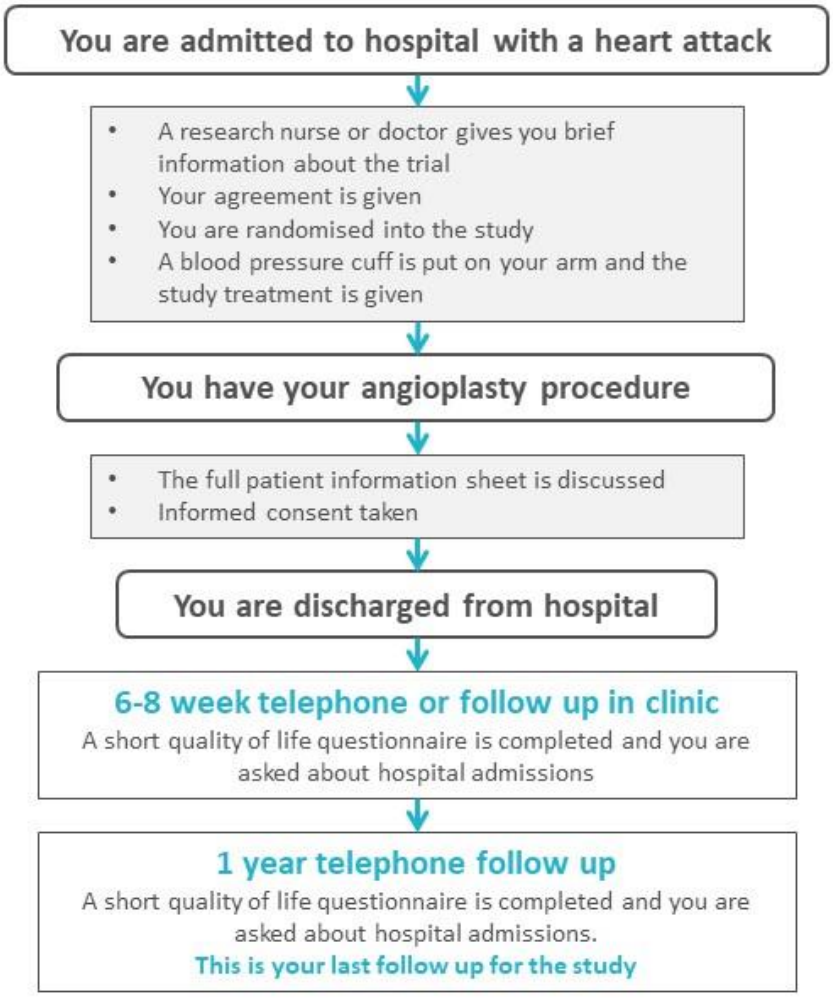
We will record some of the data that is collected as part of your normal care during your stay in hospital.

If you return for a follow up visit at your hospital (this is usually 6 to 8 weeks after you are discharged) we will ask you some questions. The questions will be about whether you have had any heart related hospital admissions or any changes to your treatment. If we need further information on any hospital admissions we will look at your hospital notes. The notes will be reviewed from where you had your hospital admission. We may need to contact your GP for further information. If you do not attend the hospital you will be asked these questions over the telephone. Any information on hospital admissions will again be collected from your hospital notes or your GP. You will be asked to complete a short questionnaire about your quality of life at your hospital appointment. This will be done by telephone or post if you do not attend the hospital.

A member of the research team will then call you 12 months after your angioplasty to see if you have had any other admissions to hospital. At this point it may also be necessary for the nurse to ask your GP or your local hospital for further information. You will also be asked to complete a short questionnaire about your quality of life and this can either be posted to you or completed over the telephone. Your direct involvement in the study is finished 12 months after your admission to hospital with your heart attack.

Information about your health status from the NHS Health and Social Care Information Centre (HSCIC) will be collected for up to 10 years after you are admitted to hospital. We will not need to contact you about this.

Below is a flowchart which summarises the study:


You are admitted to hospital with a heart attack
A research nurse or doctor gives you brief information about the trial
Your agreement is given
You are randomised into the study
A blood pressure cuff is put on your arm and the study treatment is given
You have your angioplasty procedure
The full patient information sheet is discussed
Informed consent taken
You are discharged from hospital
6-8 week telephone or follow up in clinic
A short quality of life questionnaire is completed and you are asked about hospital admissions
1 year telephone follow up
A short quality of life questionnaire is completed and you are asked about hospital admissions.
This is your last follow up for the study

Will all patients undergo the study treatment?

No. There will be two separate groups. Half of the patients will have received the RIC and the other half have not (this is the **control** group). Patients in both groups will have had an identical looking cuff applied immediately before angioplasty.

The cuff applied to patients in the **RIC** group inflates continuously for a five minute period on your arm. After which it deflates for five minutes. This cycle of inflation, followed by deflation is performed four times in total.

The cuff applied to patients in the **control** group will not inflate and the cycles of inflation and deflation are simulated.

RIC is a safe procedure that has been carried out in thousands of people.

No drugs are being tested in this study, only the effects of the cuff inflation.

How was my treatment decided?

The choice of treatment was selected at random (via a computer program) rather than by your doctor. This is called randomisation. The process of randomisation makes the study scientifically strong and allows the findings to be used to guide treatment of patients in the future. Half of the patients are in the RIC group, the other half is in the control group. You had a 50% (or 1 in 2) chance of getting the RIC.

Will I know which treatment I will receive?

No. The patients and doctors at each hospital are not told which group you are in. This is to ensure that the results of the study are scientifically strong.

Is there any risk?

Blocking the blood supply to the arm for 5 minutes will not cause any damage. This procedure has been used on several thousand patients (including children) and in healthy volunteers without any harmful effects on the arm.

There may have been slight discomfort from the inflation of the blood pressure cuff.

There may have been some small red spots over the arm. This is called skin petechiae and is caused by the blood pressure cuff bursting blood vessels in the skin. This may last for a few days. Skin petechiae is rare and does not cause any harm.

You were also given a drug called Adenosine to increase blood flow in the heart arteries. Patients can feel some chest tightness or shortness of breath when given this drug. These effects are short lasting and stop within a few seconds of stopping the drug.

Will extra blood samples be collected?

No, the blood samples that are taken as part of your normal care are all that will be taken.

Will any other extra tests be done?

No, the tests that you receive as part of your normal care at hospital are all you will receive.

What are the potential benefits?

We cannot promise the study will help you but the information we collect may help improve the treatment of people who have a heart attack in the future. It will also provide further insight into whether RIC is effective.

Will my taking part be kept confidential?

Yes. All the information about your 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 collecting and analysing the data. We will need to look at parts of your medical records. You 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 will be sent a copy of your consent form to make sure it has been completed correctly.

Your NHS number will be shared with the NHS Health and Social Care Information Centre (HSCIC) in order to help contact you or provide information about your health status. The information will be shared in accordance with HSCIC guidelines.

Will anyone else be informed of my involvement in this study?

We will ask for your permission to send a letter to your GP informing them of your involvement.

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, your research doctor/nurse will tell you about it and discuss whether you want to continue with the study.

If the study is stopped for any other reason, you will be told why and your normal hospital care will continue.

What if there is a problem?

RIC is a safe procedure that has been carried out in thousands of people without causing any harm. However, research can carry unforeseen risks and we want you to be informed of your rights in the unlikely event that any harm should occur as a result of taking part in this study.

This research is covered by a no-fault compensation scheme, which may apply in the event of any significant harm resulting from involvement in this study.

If you have any concerns about any aspects of this study, you should ask to speak to the researcher who will do their best to answer any questions. Contact information can be found at the bottom of this information sheet.

Who has reviewed the study?

An independent Research Ethics Committee has approved this research. The study had been reviewed and approved by National Research Ethics Service (NRES) Committee London - Harrow.

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 data to you personally will be used in any reports or publications.

Who is organising and funding the research?

The London School of Hygiene and Tropical Medicine is organising and running the study. The sponsor of the study is University College London (UCL). The study is funded by the British Heart Foundation (BHF), a charity. Your own doctor does not get paid anything directly for putting you into this study.

What happens if something goes wrong?

If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff you may have experienced due to your participation in the research, National Health Service or UCL complaints mechanisms are available to you. Please ask your research doctor if you would like more information on this.

In the unlikely event that you are harmed by taking part in this study, compensation may be available.

If you suspect that the harm is the result of the Sponsor's (UCL) or the hospital's negligence then you may be able to claim compensation. After discussing with your research doctor, please make the claim in writing to Professor Derek Hausenloy who is the Chief Investigator for the research and is based at UCL.
The Chief Investigator will then 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 Derek Hausenloy
University College London
The Hatter Cardiovascular Institute
67 Chenies Mews
London
WC1E 6HX

Details of how to contact the researchers

The researchers conducting this study at your hospital can be contacted using the following details:

(insert contact details)