A feasibility randomised controlled trial of mechanical chest compression devices for in-hospital cardiac arrest (COMPRESS-RCT)

PARTICIPANT INFORMATION SHEET

PART 1:

Introduction

You have been given this information sheet to read because you have recently suffered a cardiac arrest (your heart stopped beating) during your stay in hospital. The hospital where you are being treated is taking part in a research study called the COMPRESS-RCT study. During your cardiac arrest, you were enrolled in the COMPRESS-RCT study. When patients have a cardiac arrest, treatment must start as quickly as possible to keep blood circulating in the body. As a result, it was not possible to ask permission from you or your family member before you were enrolled in the study.

We would now like to invite you to take part in the follow-up phase of this study. We would like to discuss with you whether you would be willing to complete some questionnaires and allow us to collect information from your medical records.

This information sheet explains why the research is being done and what it means for you. One of our team will go through the information sheet with you and answer any questions you have. Please ask us if there is anything that is not clear.

What is the purpose of the study?

This research study is investigating the use of mechanical chest compression devices in treating people who suffer a cardiac arrest. When you had your cardiac arrest, you needed chest compressions as part of your treatment. Chest compressions are an essential treatment for patients in cardiac arrest because they keep blood circulating around the body. They are delivered by pressing down on the breastbone about 100 times per minute to a depth of two inches (five centimetres). Normally, doctors and nurses do this manually (manual chest compressions). However, mechanical chest compression devices have been developed and these can be used to provide chest compressions instead of a human.

This research study aims to find out if it is feasible to carry out a trial using mechanical chest compression devices for treating cardiac arrest in hospital. To find out if using these devices in hospitals is beneficial and help more people to recover after cardiac arrest, a large number of participants would be needed which would be very expensive. By carrying out this smaller scale study first, we will know whether it is possible to complete a larger study.

Why have I been chosen?

The hospital you were in when your cardiac arrest occurred is taking part in this study. You met the study eligibility criteria and did take part in the study. All patients were initially treated with manual chest compressions. However, some patients were then treated with the mechanical chest compression device and other patients continued to receive manual chest compressions. The decision about whether or not you were treated with the device was decided by chance. This makes sure that the study is fair. This type of study is called a randomised controlled trial.

You have already participated in the study and you **may** have received chest compressions delivered by the mechanical chest compression device. At this point we are asking for your consent to continue participating in the study.

Your participation is equally important whether the mechanical chest compression device was used or not.

You may currently be unaware whether the mechanical chest compression device was or was not used in your case. We would prefer for you to not know this information until six-months after your cardiac arrest. This is because some of the information that we are trying to collect may be affected if you know whether or not you received chest compressions provided by the mechanical device. However, if you do want to know which treatment you received, please discuss this with the hospital research team, who will be able to tell you.

What is the device that is being used?

The machine that is being used to perform mechanical chest compressions in this study is called the LUCAS device.

The LUCAS device has been approved to meet European health and safety requirements. However, we do not yet know whether using the LUCAS is better than manual chest compression for patients that have a cardiac arrest in hospital.

What will happen to me if I continue to take part? What do I have to do?

You've already received the treatment that forms part of this study- this happened at the time of your cardiac arrest. There are no further trial related treatments required. We have already collected some information about you and your cardiac arrest from your medical records.

We would like to continue monitoring your health until six-months after your cardiac arrest. This will involve us looking at your hospital medical records and may involve us talking to your General Practitioner. We would also like you to complete a questionnaire before you go home from

hospital and a further questionnaire in six-months time. These questionnaires will help us to find out how well you are recovering and what help you need with your normal everyday activities. Each questionnaire will take about ten minutes to complete.

One of the research team will visit you prior to your discharge from hospital to help you to complete the first questionnaire. The second (six-month) questionnaire will be posted to you at your home address (or another nominated address) for you to complete at your convenience and return to us. Alternatively, we can complete the 6 month questionnaire over the telephone with you. If necessary, someone that knows you well may complete the questionnaires on your behalf.

The questionnaires and continued data collection are very important to help us evaluate the effectiveness of the mechanical chest compression device. However, we understand that some people may not want to complete the questionnaires. We also understand that some people may not want us to continue to collect information from their medical records.

So that we can be clear about your continued participation in the study, we would like to offer you three choices:

OPTION ONE: You agree to allow us to continue collecting information from your medical records for up to six-months. You also agree to complete a study questionnaire before you go home and in six-months time.

OPTION TWO: You agree to allow us to continue collecting information from your medical records for up to six-months, but you decide that you do not want to complete the study questionnaires.

OPTION THREE: You decide that you do not want us to collect any further information about you.

Do I have to take part?

It is up to you to decide whether or not to continue to take part in the study. If you kindly agree to option one or option two, we will ask you to sign a consent form. If you decide that you do not want to continue to take part in the study (option three), we will use anonymised data that has already been collected, but we will not collect any further information about you.

Whatever option you select, you are free to change your mind at any time and select a different option. If you do change your mind, you do not need to give a reason.

What are the possible benefits or risks of taking part?

Most people remember very little about their cardiac arrest. The only risk that we anticipate from you continuing to take part in this trial is that very occasionally people find completing the

questionnaires upsetting. In the unlikely event that this happens to you, our trained research staff can talk to you about your feelings and offer to put you in contact with professional services if required. There will also be a modest time commitment to complete the questionnaires.

Overall, there are no significant personal direct benefits or risks associated with you continuing to participating in this research.

The information we collect from you will help to inform design of similar studies in the future and may help us work out how best to treat people with this condition

What if there is a problem?

If you have a concern about any aspect of this study, you should first speak to the local research team who will do their best to answer your questions. You can contact the research nurse on [telephone number]

This study is covered by the University of Warwick's insurance and indemnity cover. If you have any questions or concerns about the way that this trial is being carried out, please contact the chief investigator (Dr Keith Couper, Tel: [number], Email: compresstrial@warwick.ac.uk). If you remain unhappy about how you have been dealt with during the study, please address your complaint to the University of Warwick Director of Delivery Assurance (Address: Registrar's House, University House, University of Warwick, Coventry, CV4 8UW. Email: complaints@warwick.ac.uk, Tel: 02476 574774). The director of delivery assurance is a senior University of Warwick official who is independent of the research.

If you are unhappy about any aspect of your treatment, you can do this through the NHS Complaints Procedure. You can contact the local NHS Trust Patient Advice Liaison Service (PALS) by telephone [telephone number] or by email [email address]

PART 2:

What if something goes wrong?

The treatment for your cardiac arrest has already finished, so it is now extremely unlikely that anything will go wrong as a result of taking part in this trial.

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. You may have to pay your legal costs.

What will happen if I don't want to continue with the study?

We have offered three options about continuing in the study. You may change your mind at any time you wish without giving a reason and without affecting your rights or future treatment.

Will my taking part in the study be kept confidential?

Yes. 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.

We will anonymise information about you by using a study number and your initials. Information about you will be anonymised at the point that it is collected. We will securely transfer anonymised information about you, your cardiac arrest and recovery to the University of Warwick so that the study results can be analysed. All information that we collect will be stored securely in either lockable filing cabinets or password-protected computers. The information will be kept for ten years following completion of the study.

If you select option one, your contact details will be securely transferred to the University of Warwick Clinical Trials Unit to enable us to contact you six months after the cardiac arrest. Any personal identifiable information about you will only be used for this research trial. Anonymised data may be used for future research.

Who is organising and funding the research?

The study is funded by the National Institute for Health Research (NIHR), as part of a Post-Doctoral Research Fellowship award (grant number PDF-2015-08-109). The sponsor of the study is the University of Warwick.

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people. This study has been reviewed and approved by the West Midlands - Coventry and Warwickshire Research Ethics

Committee.

What will happen to the results of the research study?

The results will be published in a medical journal and may be submitted to medical conferences. You will not be identifiable in any study outputs. The results may help us to ascertain if it is feasible to carry out a large scale randomised study of mechanical chest compression devices and may help us work out how best to treat people with this condition. If you would like us to inform you of the results of the study, please tell the research team.

Involvement of General Practitioner

With your permission, we will write a letter to inform your General Practitioner of your participation in the study. We may also contact your General Practitioner prior to sending out the 6 month questionnaire to you in order to find out your health status.

Further information and contact details

If, at any time, you would like further information about this research project, please contact the local research nurse [Name and telephone number]. General study information is also available on the study website (www.warwick.ac.uk/compresstrial).

Thank you for taking the time to read this information sheet