UK REBOA TRIAL

RESUSCITATIVE ENDOVASCULAR BALLOON OCCLUSION OF THE AORTA FOR TRAUMA

PATIENT INFORMATION LEAFLET

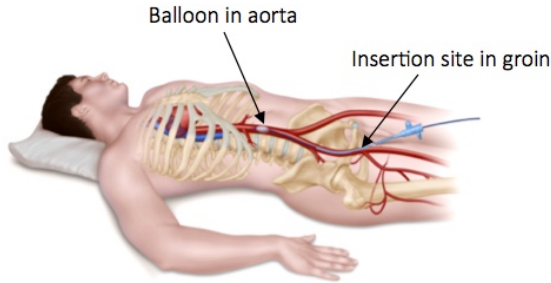
When you came into hospital, you were enrolled in a clinical research study called the UK-REBOA Trial. The necessity of immediate treatment ruled out the possibility of taking your consent, or asking a relative or friend, at the time. We are now seeking your consent for continuing to take part in the research study which will involve us gathering follow up information about you and your care. It is important for you to understand why this research is being done and what it means for you. Please take time to read the following information leaflet carefully and decide whether or not you would like to continue to take part.

Please feel free to ask us at any point if there is anything that is not clear or if you need more information, our team would be only too pleased to answer any questions you have.

WHAT IS THE PURPOSE OF THE STUDY?

We are doing research into a new treatment called "REBOA" (which stands for "Resuscitative Endovascular Balloon Occlusion of the Aorta"). Severe, uncontrolled bleeding is one of the most common causes of death following serious injury. Using REBOA may help us to stem the blood flow and "buy time" to get such patients to an operating theatre.

REBOA involves passing a small inflatable balloon into the aorta (your main artery) in order to limit further blood loss, until an operation can be performed to see what is causing the bleeding, and stop it.



This study was designed to gather data to assess whether the use of REBOA, in addition to usual treatment, improves a patient's chance of living and recovering.

WHY HAVE I BEEN CHOSEN?

You were chosen because you came to hospital with life-threatening bleeding, and the doctors who were treating you needed to control this

bleeding very quickly. At this time, the doctor who was treating you decided that you may be suitable to take part in this trial. As a result you may, or may not have been treated with REBOA during your initial care.

WAS I ASKED FOR PERMISSION TO TAKE PART?

When you were admitted to hospital, you had very serious injuries, which required immediate treatment. There was no time to explain the study to you (or even a relative or friend), and you were therefore not asked for permission at the time. This is one of the few studies which permits patients to be included without their specific consent.

DID I RECEIVE REBOA?

In some patients, we do not know whether treatment with REBOA is better than current treatment. To learn more, we need to make comparisons, and to do this, you were randomised into one of two groups: one group receives REBOA, and the other does not. So, you may or may not have received REBOA as part of your treatment at the time you were admitted. Regardless of whether you decide to give us permission to continue collecting information about you or not, you can find out whether you received REBOA as part of your treatment at the time you were admitted. On the back of this leaflet are contact details of the trial team looking after you, please contact this team for details about the treatment you received we would be happy to tell you, if you would like to know.

WHAT WILL HAPPEN TO ME IF I AGREE TO CONTINUE TO TAKE PART?

You have already received the treatment that forms part of this study at the time of your admission to hospital. As a result there are now no further trial related treatments required.

If you agree to continue to take part, we would very much like your permission to use the information which we have collected in relation to your treatment, (including details of your injuries, and what operations and other treatments you have had) and obtain certain additional information in the future. Much of this information is recorded routinely. All such data will be confidentially and securely stored by the University of Aberdeen.

In order to collect this information, we will ask the doctors and nurses to look at your NHS records.

Regardless of whether you agree to take part in our study at this time, or not, you will also receive a short questionnaire from the Trauma Audit & Research Network (TARN), around six months after your injury, to assess how well you have recovered, this questionnaire is routinely sent out to all patients like yourself, irrespective of whether you take part in this study or not. However, if you agree to take part, it would be very helpful for us be able to use this questionnaire information too.

DO I HAVE TO CONTINUE TO TAKE PART?

No. It is entirely up to you whether or not you want to continue to take part. Please remember that you have already received the treatment that forms part of this study and as a result there are now no further trial related treatments required, continuing to take part simply gives us permission to look at your data. Please take as much time you need to make this decision. You can keep this information leaflet and ask your doctor and/or research nurse as many questions as you like.

If you do decide to continue to take part you will be asked to sign a form giving your consent for this. Even after signing this form, you are still free to withdraw from the study at any time without giving a reason and your data will not be used. At no point will your decision affect the standard of care you receive now or in the future.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

By taking part, you will be helping us to accumulate more information about REBOA so we can better treat future patients with life-threatening bleeding caused by injury.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

The risks from you continuing in the trial are small. Although most people with life-threatening haemorrhage remember very little about

their initial treatment, receiving a questionnaire or a visit from a researcher could be upsetting. Our trained research staff can talk to you about any such feelings and can offer to put you in contact with professional services if required.

WHAT IF THERE IS A PROBLEM?

If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek compensation through the NHS.

As a patient of the NHS, if you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms are available to you.

If you have a concern about any aspect of the study, you can ask to speak with the research team who will do their best to answer your questions (contact details of your local study nurse and the Study Office can be found at the end of this information sheet, which is for you to keep). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.

WHO WILL KNOW I AM TAKING PART IN THE STUDY?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard the privacy of the patient at every stage. Only certain members of the research team will have access to your information in order, for example, to send you the questionnaires.

We will tell your GP you are taking part, but only with your permission.

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the sponsors, the NHS Research & Development Department of your local hospital, and the Regulatory Authorities whose roles it is to check this research is properly conducted and the interests of those taking part in this study are protected. All of these individuals are under a duty to keep your records confidential.

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, and will be held securely in accordance with the Data Protection Act 1998. Your information will be stored using a unique study number for confidentiality and will be kept secure using passwords.

In this study, we aim to collect relevant readmission hospital data from the NHS central registers: in England this is NHS Digital. The reason for this is to make sure that we have the correct information about all the participants taking part in this study and ensure that the results are as accurate as possible. In order to do this, we would need to securely send the NHS central registers some information about you (e.g. date of birth, name, and address). They will then match this information to their records and using your study number securely send any hospital readmission data back to the Trial Office. Data will also be collected from the national Trauma and Research Network, in a similar manner.

Other researchers may wish to access data from this study in the future. However, it will not be possible to identify participants from this data because it will not include names, addresses or dates of birth. The consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You can decide at any time not to carry on with this study, but you should continue attending appointments with your consultant and/or GP as part of your standard care. If you do not want us to use the data collected, it will not be used.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be used to make recommendations on the treatment for patients with life-threatening bleeding caused by injury. We shall publish the results of this study in scientific journals and present the information at appropriate meetings. You will not be identified in any publication of results of the study.

WHO IS ORGANISING AND FUNDING THE STUDY?

This study is sponsored by the University of Aberdeen and NHS Grampian who have overall responsibility for the management of the study. The study is funded by the National Institute of Health Research. The research is being carried out by a group of experienced researchers from the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen, and a group of expert clinicians and researchers from throughout the United Kingdom.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC) to protect your interests. This study has been reviewed and approved by North West Greater Manchester South ethics committee.

Thank you for reading this

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to continue to participate in the UK-REBOA Trial. Please ask us if you have questions or would like more information about the study.

FURTHER INFORMATION AND CONTACT DETAILS

If you have any questions or would like any more information, please contact:

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Local Centre contact details