The impact of **RES**trictive vers**U**s LIbera**L** **T**ransfusion strategy on cardiac injury and death in patients undergoing surgery for **Hip** Fracture (RESULT-Hip)

**Participant Information Sheet**

**Recovered Capacity**

**England, Wales and Northern Ireland (RUK)**

During your hospital admission you were unable to give consent for entry into this research study. You were entered into the research study by a process approved by the research ethics committee. This is permissible under the Mental Capacity Act 2005 and Mental Capacity Act (Northern Ireland) 2016. As part of this process we asked a personal or nominated consultee for their opinion about whether you would want to be involved in the study. You were eligible to take part because you were being treated in hospital for a broken hip and blood tests showed that you were anaemic (had a low level of haemoglobin in your red blood cells or a “low blood count”).

Before you decide whether to continue to take part, 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. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether you wish to take part.

Thank you for your time



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| **What is the purpose of the study?** |
| People with broken hips often need a blood transfusion during their hospital stay. This is because they often have a low blood count (anaemia) before they come into hospital or because of their injury or because they lose blood during the operation to fix their hip.  Although some research has been done in this area, doctors are uncertain about the best time to prescribe blood transfusions to people with a broken hip. Most guidelines suggest that prescribing at a lower blood count is better for patients in hospital and recommended standard treatment is for patients to receive a blood transfusion when their blood count is less than 70 -80 g/L. Some doctors think that this level is too low particularly if the participant is known to have heart disease. We are undertaking a study to compare blood transfusion at two different levels of anaemia to see which one is best.  Everyone in our hospital with a broken hip will be assessed to see if they can take part in this study. If they become anaemic during their treatment they will be allocated to either receive a transfusion straight away or wait until the blood count falls to a lower level. We then closely monitor participant’s recovery from surgery, including any complications they might have. |
| **Why was I invited to take part?** |
| You had surgery in our hospital for treatment of a fractured hip and a personal consultee or nominated consultee advised us that you would have no objection to joining the study. However, you are now capable of making an informed decision about whether you wish to continue on the study. |
| **Do I have to continue to take part?** |
| No, it is up to you to decide whether to continue taking part. If you do decide to continue, you are free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights. |
| **What will happen if I take part?** |
| After you were enrolled in the study, you became anaemic (blood count 90g/L or less) and we used a computer to randomly decide which of two different approaches to treating anaemia with blood transfusions to use while you remain in hospital.  The two groups are   |  |  | | --- | --- | | Lower blood count group | Higher blood count group | | Participants receive blood transfusions to treat their anaemia and allow their **red blood cell count to be at a lower level**  **(between 75 – 90g/L)** | Participants receive blood transfusions to treat their anaemia and keep their **red blood cell count at a higher level**  **(between 90- 110g/L)** |   You are in one of the two groups and will receive blood transfusions according to that group until you are discharged from hospital or until 30 days whichever is sooner.  Everyone in the study had their blood tested at the start to check their haemoglobin level and kidney function. These blood tests are repeated after participants enter the study and we measure participant’s haemoglobin after every blood transfusion. As much as possible we take the samples for the tests at the same time as routine hospital blood samples.  Everyone in the study had blood samples taken when they entered the study and twice more between days 1 and 5 to check their heart. Each blood sample takes about a teaspoon of blood (5ml). The blood samples are frozen and stored at your hospital for several months before being sent to the University of Edinburgh for testing. The test is very sensitive and is to check the heart. The results of the blood test will be used in our research to find out if it is significant in the setting of a broken hip .We will not be able to share the results of the blood tests with the doctors looking after you as they will not be available for about a year after hospital admission and so will not be useful to the doctors managing your hospital care. We would like to keep these blood samples after the end of the study for further research but will only do so with your permission. If you change your mind and later decide that you do not want your samples being used in future research, please tell us and we will destroy the samples.  A heart tracing (known as an electrocardiogram or ECG) was taken at the start of the study and repeated one more time between days 2 and 5 afterwards. As well as the blood tests and ECG, a member of the research team will ask you a few questions about how you are feeling to detect if you are at risk of developing delirium (becoming confused). This is called a 4AT test. We do this test when you enter the study and twice more between days 1 and 5.  When you entered the study, we asked your personal consultee to complete a short questionnaire about the quality of your life before you broke your hip. If you have recovered capacity, we will ask you the same questions at 1 and 4 months afterwards plus an additional short questionnaire about your use of health services. A member of the research team will contact you by telephone to ask you the questions. We will post the questionnaires if we are unable to contact you by telephone. We will also use information collected in your medical notes during your hospital stay and for up to four months. All data for the study will be identified by anonymous codes rather than your name.  If you agree to take part but then later become so unwell that you are unable to consent during the course of your hospital stay, we will keep you enrolled in this study. |
| **Is there anything I need to do or avoid?** |
| No, there are no special precautions or requirements you need to take. |
| **What are the possible benefits of taking part?** |
| There are no direct benefits to you taking part in this study, but the results from this study might help to improve the healthcare of patients like you in the future. |
| **What are the possible disadvantages of taking part?** |
| At the moment there is uncertainty how best to treat anaemia with blood transfusions for people with a hip fracture and either of the approaches used in this study might be used by doctors. Correcting anaemia with blood transfusions (the ‘liberal’ group in our trial) might help heart function and give people more energy to get out of bed. However, any blood transfusion also carries small risks.  These include, breathing problems and rare transfusion reactions (for example a fever or rash). Serious complications are very rare indeed.  We currently don’t know whether a higher or lower blood count level is best for reducing complications overall and improving your recovery after surgery, which is why we are doing this trial. We will closely monitor what happens to participants in both groups to make sure that we find out about any problems quickly and treat them appropriately. If you were to need an emergency blood transfusion, for example due to bleeding, your doctors would be able to give it to you, whatever your blood count. |
| **What if there are any problems?** |
| If you have a concern about any aspect of this study please contact <insert name and contact details here> who will do their best to answer your questions.  In the unlikely event that you are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation against NHS XXXX but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). |
| **What will happen if I don’t want to carry on with the study?** |
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| You are free to withdraw your consent to participate in this study **at any time** without giving a reason and any study treatment would be stopped. This would not affect the standard of care you receive in any other way or your legal rights.  The options for withdrawal are :   1. Withdrawal from intervention only – permission given to contact participant for follow up questionnaires and to collect information from routine health records for the primary & some secondary outcomes 2. Withdrawal from intervention and any on-going aspects of the trial that require participant contact or completion of questionnaires but permission given to collect information from routine health records for the primary & some secondary outcomes 3. Withdrawal from all aspects of the trial but continued use of data up to that point |
| **What happens when the study is finished?** |
| You will be involved in the study until you have completed the 4 month follow up. We plan to publish the results shortly after all the follow-ups have been completed through medical publications, websites, and press releases. Individual participants will not be identifiable in any published results. We would like to contact you at the end of the trial with a summary of the results but will only do so if you have no objection.  We will make a summary of the findings of our study available on our website:  <https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/all-current-studies/RESULT-Hip> |
| **Will my taking part be kept confidential?** |
| All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. The steps to protect your data are described at the end of this leaflet. We have written to your General Practitioner (GP) to let them know that you are taking part in the study. |
| **Who is organising and funding the research?** |
| This study has been sponsored by the University of Edinburgh and NHS Lothian. The study is being funded by the National Institute for Healthcare Research – Health Technology Assessment (NIHR – HTA). |
| **Who has reviewed the study?** |
| All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from Scotland A Research Ethics Committee and XXXXXXXXXXXX Research Ethics Committee. NHS Management Approval has also been given. Former participants and relatives and the Lothian Patient Advisory Group also helped us design this trial. |
| **Researcher Contact Details** |
| If you have any further questions about the study please contact  <insert name> on <insert phone number> or email on: <insert email address>. |
| **Independent Contact Details** |
| If you would like to discuss this study with someone independent of the study please contact:  <insert contact details>. |
| **Complaints** |
| If you wish to make a complaint about the study please contact:  <insert contact details> to be adapted depending on research site.  Find below the example for NHS Lothian  Patient Experience Team  2 – 4 Waterloo Place, Edinburgh, EH1 3EG  [feedback@nhslothian.scot.nhs.uk](mailto:feedback@nhslothian.scot.nhs.uk)  0131 536 3370 |

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| **Further information on Data Protection arrangements**  All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.  We have written to your General Practitioner (GP) to let them know that you are taking part in the study.  All information and samples will be stored by the University of Edinburgh and the Edinburgh Clinical Trials Unit. They would only be transferred to other researchers after all necessary approvals were in place.  In order to monitor and audit the study we will ask your consent for research representatives from the study sponsors to access your medical records and data collected during the study, where it is relevant to taking part in this research.  We may link records about you with nationally held databases to find out about your health status over a longer period without having to contact you directly, but this would only be done after all necessary approvals were in place. In order to identify you on these databases we will collect your Community Health Index (CHI) number (participants in Scotland only) or your hospital number (for all other UK participants). The Community Health Index (CHI) is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index.  **How will we use information about you?**  We will need to use information from you and from your medical records for this research project.  This information will your:   * Name and Initials * Contact details - Address, Telephone number; * Gender * Ethnicity * Date of Birth * NHS or CHI (Community Health Index) number (participants in Scotland only).   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. * If you choose to stop your taking part in the study, we would like to continue collecting information about your health from your hospital and central NHS records. If you do not want this to happen, tell us and we will stop. * 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. * If you agree to take part in this study, you will have the option to take part in future research using the data saved from this study.  **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/](https://www.hra.nhs.uk/information-about-patients/) * our leaflet available from [[**www.hra.nhs.uk/patientdataandresearch**](http://www.hra.nhs.uk/patientdataandresearch) * by asking one of the research team * by contacting the Data Protection Officer at either * University of Edinburgh. Email [dpo@ed.ac.uk](mailto:dpo@ed.ac.uk) or call 0131 651 4114 * NHS Lothian : [Lothian.DPO@nhs.net](mailto:Lothian.DPO@nhs.net) or call 0131 465 5444  **Future Studies** If you take part in this study, there are options to take part in future research using data saved from this study. This research may use identifiable data and/or blood samples or it may use non-identifiable (anonymised) data. Generally, data would only be shared with researchers within the United Kingdom. However, some research involves collaborating with researchers in different countries. In these studies, non-identifiable data may be shared with researchers outside the United Kingdom. We will only share your data if you give us permission. |

The impact of **RES**trictive vers**U**s LIbera**L** **T**ransfusion strategy on cardiac injury and death in patients undergoing surgery for **Hip** Fracture (RESULT-Hip)

**PARTICIPANT CONSENT FORM**

**Recovered Capacity**

**England, Wales and Northern Ireland (RUK)**

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|  | | Please **initial** box |
|  | 1. I confirm that I have read and understand the information sheet (Version 3 03May2023) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. | ⬜ |
|  | 1. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care and/or legal rights being affected. | ⬜ |
|  | 1. I give permission for the research team to access my medical records for the purposes of this research study. | ⬜ |
|  | 1. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records. | ⬜ |
|  | 1. I give permission for my personal information (including name, address, date of birth, telephone number and consent form) to be passed to the University of Edinburgh and/or Edinburgh Clinical Trials Unit for administration of the study. | ⬜ |
|  | 1. I give permission for my Community Health Index (CHI) number/hospital number to be collected and passed to the University of Edinburgh and/or Edinburgh Clinical Trials Unit. | ⬜ |
| 1. I agree to my General Practitioner (GP) being informed of my participation in this study. | ⬜ |
|  | 1. I understand that data collected about me during the study may be converted to anonymised data. | ⬜ |
|  | 1. I agree to give blood samples for this study which will be used for research purposes. | ⬜ |
|  | 1. I agree to my identifiable data and/or blood samples being used for future ethically approved studies within the UK. | Yes ⬜ No ⬜ |
|  | 1. I agree to my anonymised data and/or blood samples being used in future studies within the UK. | Yes ⬜ No ⬜ |
|  | 1. I agree to my anonymised data and/or blood samples being used in future studies outwith the UK. | Yes ⬜ No ⬜ |
|  | 1. I agree to being contacted by researchers from the University of Edinburgh at the end of the study with a summary of the trial results. | Yes ⬜ No ⬜ |
|  | 1. I agree to take part in the above study | ⬜ |

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| Name of Person giving Consent | Date | Signature |
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| Name of Person Receiving Consent | Date | Signature |

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record

**PARTICIPANT CONSENT FORM**

**RECOVERED CAPACITY**

**England, Wales and Northern Ireland (RUK)**

***If consent was taken verbally this section must also be completed***

Reason for using verbal consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(print witness name) confirm that I / a member of the research team\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (print name of researcher) have read and explained the content of the PIS (Version 3 03May2023) and confirm that \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of participant) has had any questions answered. I confirm that to the best of my knowledge they understand this information and is willing to participate

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Name of person giving verbal consent

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Name of person receiving consent Signature Date

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Name of person witnessing consent Signature Date

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record