The impact of REStrictive versUs LIberaL Transfusion strategy on cardiac injury and death in patients undergoing surgery for Hip Fracture (RESULT-Hip)

**Participant Information Sheet**

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

You are being invited to take part in a research study. You are eligible to take part because you have are being treated in hospital for a broken hip (hip fracture). Before you decide whether 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. Their recovery from surgery, including any complications they might have, will be closely monitored. |
| **Do I have to take part?** |
| No, it is up to you to decide whether to take part. If you agree, you will be given this information sheet to keep and be asked to sign a consent form. If you agree, 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?** |
| If you agree to take part in the study we will monitor your blood count and if you become anaemic (blood count 90g/L or less) in the period between admission and 7 days after your surgery, we will use a computer to randomly assign you to one of two transfusion groups. If you do not become anaemic you will not be entered into the study and we will have no further contact with you.  The two groups are:   |  |  | | --- | --- | | Lower blood count group | Higher blood count group | | Participants will 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 will receive blood transfusions to treat their anaemia and keep their **red blood cell count at a higher level (between 90- 110g/L)** |   You will receive blood transfusions according to your group until you leave hospital or until 30 days, whichever is soonest.  You will have your blood tested at the start to check your haemoglobin level and kidney function. These blood tests will be repeated after you enter the study and we will measure your haemoglobin after every blood transfusion. As much as possible we will take these samples with your routine blood tests.  You will have a blood sample taken when you enter the study and twice more between days 1 and 5 to check your heart.  Each blood sample takes about a teaspoon of blood (5ml). The blood samples will be 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 your 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 your 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 give permission for us to keep the blood samples for further research but then later change your mind and want to withdraw your permission, please tell us and we will destroy the stored blood samples.  A heart tracing (known as an electrocardiogram or ECG) will be taken at the start of the study and then repeated once more between days 2 and 5 after you have been entered into the study. 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 when you enter the study and twice more between days 1 and 5 to detect if you are at risk of developing delirium (becoming confused). This is called a 4AT test.  We will also ask you to complete a short questionnaire about the quality of your life before you broke your hip when you enter the study. A member of the research team will contact you by telephone at 1 and 4 months afterwards to ask you to complete the same short questionnaire plus an additional one about your use of health services. We will post the questionnaires to you 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. |
| **What are the possible benefits of taking part?** |
| Taking part in this study may help to improve outcomes for patients who are anaemic following surgery for a broken hip 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 – local research team>  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 – Local Trust >>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** |
| You are free to withdraw your consent to participation **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 the study intervention only, with permission given to contact participant for follow up questionnaires and to collect information from routine health records for the primary & some secondary outcome. 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 your 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. If you have given us permission we will send you a summary of the results at the end of the study. 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 will write to your General Practitioner (GP) to let them know that you have agreed to take part in the study. |
| **Who is organising and funding the research?** |
| This 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 Programme (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 <<insert name >> Research Ethics Committee. NHS Management Approval has also been given. Former patients 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:  <<Researcher contact details>> |
| **Independent Contact Details** |
| If you would like to discuss this study with someone independent of the study please contact <insert name and 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 536 337 |
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| **Further information on Data Protection arrangements**  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 include your   * Name and Initials * Contact details - Address, Telephone number; * Gender * Ethnicity * Date of Birth * NHS and/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 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 will not 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 your 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/ [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/) * from 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), Tel 0131 651 4114 or NHS Lothian (email [Lothian.DPO@nhs.net](mailto:Lothian.DPO@nhs.net), Tel 0131 465 5444)   **Future Studies**  If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. This research may use your identifiable data and/or blood samples or it may use non-identifiable (anonymised) data. Generally, your data would only be shared with researchers within the United Kingdom. However, some research involves collaborating with researchers in different countries. In these studies, your non-identifiable data may be shared with researchers outside the United Kingdom. We will only share your data with your permission. |
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The impact of REStrictive versUs LIberaL Transfusion strategy on cardiac injury and death in patients undergoing surgery for Hip Fracture (RESULT-Hip)

**PARTICIPANT CONSENT FORM**

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

**Please initial in box**

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|  | 1. I confirm that I have read and understand the information sheet (Version 4 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 I will be allocated to one of two transfusion groups (randomised) if my blood count falls to 90g/L or less. | ⬜ |
|  | 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 United Kingdom | Yes ⬜ No ⬜ |
|  | 1. I agree to the University of Edinburgh contacting me at the end of the study with a summary of the study results. | Yes ⬜ No ⬜ |
|  | 1. I agree to take part in the above study | ⬜ |

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

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

**PARTICIPANT CONSENT FORM**

**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 4 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

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