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)

**Personal Consultee Information Sheet**

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

Your relative/friend (referred to as ‘relative’ from now on) is unable to decide for themselves whether to participate in this research study.

To help us to decide if they should join the study, we’d like to ask your opinion about whether they would want to be involved. We will ask you to consider what you know of their wishes and feelings, and to consider their best interest.

If you advise us that your relative would have no objection to taking part we will ask you to read and sign the consultee declaration on the last page of this information leaflet. We will give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative should be withdrawn from the study.

If you advise us that your relative would not wish to take part it will not affect the standard of care they receive in any way.

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 consider whether your relative would 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 has a history of 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 will then closely monitor their recovery from surgery including any complications they might have. |
| **Why has your relative been invited to take part?** |
| Your relative has been asked to take part as they have a broken hip (hip fracture).  However, they currently lack the capacity to make an informed decision about whether they can take part in a research study. We are therefore asking your opinion about whether they would want to be involved. This is permissible in England and Wales under the Mental Capacity Act (2005) and in Northern Ireland under the Mental Capacity Act (2016). Please put your own feelings about the research aside and consider the present and past wishes and feelings of your relative. |
| **Does my relative have to take part?** |
| No, they do not have to take part. If you advise us that you think your relative would have no objection to taking part you will be given this information sheet to keep and be asked to sign the declaration at the end. You are free to ask us to withdraw your relative at **any time** without giving a reason. Not taking part or withdrawing from the study will not affect the healthcare your relative receives, or their legal rights. |
| **What will happen to your relative if they take part in the study?** |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | If your relative takes part in the study, we will monitor their blood count and if they become anaemic (blood count 90g/L or less) in the period between admission and 7 days after their surgery, we will use a computer to randomly assign them to one of two groups. If they do not become anaemic then they will not be entered into the study and we will have no further contact with you about the study.  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)** |   They will receive blood transfusions according to their group until they leave hospital or until 30 days, whichever is soonest.  Everyone in the study will have their blood tested at the start to check their haemoglobin level and kidney function. These blood tests will be repeated after they enter the study and we will measure their haemoglobin after every blood transfusion. As much as possible we will take these samples with routine blood tests.  Everyone in the study will have blood samples taken when they enter 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 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 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 your relative as they will not be available for about a year after hospital admission and so will not be useful to the doctors managing their hospital care. We would like to keep these blood samples after the end of the study for further research but will only do so if you think your relative would have no objection. . If you change your mind and later advise us that your relative would object to their samples being used in future research, please tell us and we will destroy the 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 your relative has been entered into the study. As well as the blood tests and ECG, a member of the research team will ask your relative a few questions about how they are feeling when they enter the study and twice more between days 1 and 5 to detect if they are at risk of developing delirium (becoming confused). This is lled a 4AT test.  When your relative enters the study we will ask you to complete a short questionnaire about the quality of their life before they broke their hip. This questionnaire is repeated at 1 month and 4 months after your relative enters the study to measure how they are recovering. There is also a short health resources use questionnaire for completion at 1 and 4 months after your relative enters the study.  If your relative regains capacity they will be asked if they consent to continue with the study and, if they agree, we will contact them by telephone at 1 and 4 months after the date they entered the study to ask them to complete the questionnaires. We will post the questionnaires if we are unable to contact them by telephone.  In case your relative is discharged from hospital before regaining capacity, we would like your permission to collect **your** name, address and telephone number so that we can contact you at 1 and 4 months.  At 1 month after entry into the study  A member of the research team will telephone you to ask if your relative has regained capacity. If they have, the research team will contact your relative to discuss their continued participation in the study. If they wish to continue, they will be posted a Recovered Capacity consent form for completion and return. They will be asked to complete the two questionnaires by telephone, or by post if they prefer.  If they have not recovered capacity, the member of the research team will ask you to complete the two questionnaires on your relative’s behalf either by telephone, or by post if you prefer.  At 4 months after entry into the study  If your relative has not recovered capacity at 1 month after entering the study, we will contact you at 4 months and follow the same procedure as detailed above for 1 month.  We will also use information collected in your relative’s medical notes during their hospital stay and for up to four months. All data for the study will be identified by anonymous codes rather than your relative’s name. | |
| **What are the possible benefits of taking part?** |
| There are no direct benefits to your relative taking part in this study, but the results from this study might help to improve the healthcare of patients like your relative 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 relative’s 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 your relative were to need an emergency blood transfusion, for example due to bleeding, their doctors would be able to give it to them, whatever their 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 your relative is 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 your relative (if appropriate). |
| **What will happen if I don’t want my relative to carry on with the study** |
| You are free to ask for your relative to be withdrawn from participation 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 your relative receives in any other way or their legal rights.  The options for withdrawal are:   1. Withdrawal from intervention only – your relative will be contacted for follow up questionnaires and information will be collected 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?** |
| |  | | --- | | Your relative will be involved in the study until they have completed their 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 your relative at the end of the trial with a summary of the results but will only do so if you think they would 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 taking part in the study 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 relative’s privacy at every stage. The steps to protect their data are described at the end of this leaflet. We will write to their General Practitioner (GP) to let them know that they are taking part in this 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 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 <<XXXXXXXX>> 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 relative’s privacy at every stage. We will write to your relative’s General Practitioner (GP) to let them know that they 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, research representatives from the study sponsors may access your relative’s medical records and data collected during the study, where it is relevant to taking part in this research.  We may link records about your relative with nationally held databases to find out about their health status over a longer period without having to contact them directly, but this would only be done after all necessary approvals were in place. In order to identify your relative on these databases we will collect their Community Health Index (CHI) number (participants in Scotland only) or their 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 your relative?**  We will need to use information from your relative’s medical records for this research project.  This information will include your relative’s   * 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 relative’s records to make sure that the research is being done properly.  People who do not need to know who your relative is will not be able to see their name or contact details. Their data will have a code number instead.  We will keep all information about your relative 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 your relative took part in the study. **What are your choices about how your relative’s information is used?**  * You can advise us to stop your relative being part of the study at any time, without giving a reason, but we will keep information about them that we already have. * If you advise us to stop your relative taking part in the study, we would like to continue collecting information about their health from their hospital and central NHS records. If you do not want this to happen, tell us and we will stop. * We need to manage your relative’s 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 your relative * If you advise us that your relative would want to take part in this study, we will ask you if you think they would want to take part in future research using the data saved from this study.  **Where can you find out more about how your relative’s information is used?** You can find out more about how we use your relative’s 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** * 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 your relative takes 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 relative’s data if you think they would have no objection to this. |

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)

**PERSONAL CONSULTEE DECLARATION FORM**

**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 5 09Aug2023) 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 relative will be allocated to one of two transfusion groups (randomised) if their blood count falls to 90g/L or less. | ⬜ |
|  | 1. I understand that my relative’s participation is voluntary and that I am free to request my relative’s withdrawal at any time without giving any reason and without my relative’s medical care and/or legal rights being affected. | ⬜ |
|  | 1. I understand that the research team will access my relative’s medical records for the purposes of this research study | ⬜ |
|  | 1. I understand that relevant sections of my relative’s 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 relative’s taking part in this research. | ⬜ |
|  | 1. I understand that my relative’s personal information (including name, address, and date of birth, telephone number and personal consultee declaration form) will be passed to the University of Edinburgh and Edinburgh Clinical Trials Unit for administration of the study. | ⬜ |
|  | 1. I understand that my relative’s hospital number will be collected and passed to the University of Edinburgh and Edinburgh Clinical Trials Unit. | ⬜ |
| 1. I agree for my personal information (name, address and telephone number) to be collected and passed to the University of Edinburgh and Edinburgh Clinical Trials Unit for administration of the study. | ⬜ |
|  | 1. I understand that my relative’s General Practitioner will be informed of their participation in this study. | ⬜ |
|  | 1. I understand that data collected about my relative during the study may be converted to anonymised data. | ⬜ |
|  | 1. I understand that my relative will provide blood samples for this study which will be used for research purposes. | ⬜ |
|  | 1. In my opinion my relative would have no objection to their identifiable data and/or blood samples being used for future ethically approved studies within the UK | Yes ⬜ No ⬜ |
|  | 1. In my opinion my relative would have no objection to their anonymised data and/or blood samples being used in future studies within the UK | Yes ⬜ No ⬜ |
|  | 1. In my opinion my relative would have no objection to their anonymised data and/or blood samples being used in future studies outwith the UK. | Yes ⬜ No ⬜ |
|  | 1. In my opinion my relative would have no objection 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. In my opinion, my relative would have no objection to taking part in the above study. | ⬜ |

I confirm that I am the personal consultee for ­­­­­­­­­­­­­­­­­

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Relationship to participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Name of Personal Consultee Signature Date

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Name of person undertaking consultation Signature Date

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