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)

**Nominated Consultee Information Sheet**

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

This patient is eligible to take part in this research study because they are to have surgery for a hip fracture. Unfortunately they lack mental capacity at the moment to be able to decide for themselves whether to take part in this research. We are therefore asking you to take the role of nominated consultee and consider on their behalf whether they should join the study. This is permissible in England and Wales under the Mental Capacity Act 2005, and in Northern Ireland under the Mental Capacity Act 2016.

To help you advise whether this patient should take part, it is important for you to understand why the research is being done and what it will involve. 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 before you make a decision about what advice you give us. We would then ask that you put your own views about the research aside and consider what you think the past and present wishes and feelings of this patient would have been had they been able to consent for themselves.

If you advise that in your opinion this patient would be content to join the study, 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you fully informed during the study so you can let us know if you have any concerns or you think this patient should be withdrawn from the study.

If you advise this patient should not take part it will not affect the standard of care they receive in any way

Thank you for your time

|  |
| --- |
| **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 patient 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. |
| **Does this patient have to take part?** |
| No, . if you advise us that this patient should take part you will be given this information sheet to keep and be asked to sign the declaration at the end of this leaflet. You are still free to ask us to withdraw this patient **at any time** without giving a reason.  |
| **What will happen to this patient if they take part in the study?** |
|

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| If this patient 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 post-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 them.The two groups are:

|  |  |
| --- | --- |
| Lower blood count group | Higher blood count group |
| Patients 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)** | Patients will receive blood transfusions to keep their **red blood cell count at a higher level****(between 90- 110g/L)** |

They will remain in the group they have been assigned to 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 this patient 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 this patient would have no objection. If you change your mind and later advise us that this patient 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 this patient has been entered into the study. As well as the blood tests and ECG, a member of the research team will ask this patient 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 called a 4AT test.We will also use information collected in this patient’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 this patient’s name. If a personal consultee becomes available for this patient, we will ask them for their opinion about whether this patient would wish to be included in the study at the earliest opportunity.  |

If this patient regains capacity they will be asked if they consent to continue with the study. |
| **What are the possible benefits of taking part?** |
| There are no direct benefits to this patient taking part in this study, but the results from this study might help to improve the healthcare of patients 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 the patient’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 participants 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 this patient is harmed during the research and this is due to someone’s negligence then they may have grounds for a legal action for compensation against NHS XXXX but they may have to pay their legal costs. The normal National Health Service complaints mechanisms will still be available to this patient (if appropriate). |
| **What will happen if I don’t want this patient to carry on with the study ?** |
| You are free to ask for this patient to be withdrawn from this study **at any time** without giving a reason and any study treatment would be stopped. This would not affect the standard of care this patient receives in any other way or their legal rights. The options for withdrawal are:1. Withdrawal from intervention only – the participant 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 patient 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?** |
|

|  |
| --- |
| This patient 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 patients will not be identifiable in any published results. We would like to contact this patient 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 this patient’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 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 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 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 <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 Team2 – 4 Waterloo Place, Edinburgh, EH1 3EG feedback@nhslothian.scot.nhs.uk 0131 536 3370 |

|  |
| --- |
| **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 this patient’s privacy at every stage. We will write to this patient’s General Practitioner (GP) to let them know that they are taking part t 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 this patient’s medical records and data collected during the study, where it is relevant to taking part in this research.We may link records about this patient 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 this patient on these databases we will collect their Community Health Index (CHI) number (patients in Scotland only) or their hospital number (for all other UK patients). 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 this patient?** We will need to use information from this patient’s medical records for this research project. This information will include:* Name and Initials
* Contact details - Address, Telephone number;
* Gender
* Ethnicity
* Date of Birth
* NHS or CHI (Community Health Index) number (patients in Scotland only). This number uniquely identifies a person on the index.

People will use this information to do the research or to check this patient’s records to make sure that the research is being done properly.People who do not need to know who this patient 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 this patient 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 this patient took part in the study.**What are your choices about how this patient’s information is used?*** You can advise us to stop this patient 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 this patient 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 this patient’s 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 them...
* If you advise us that this patient 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 this patient’s information is used?**You can find out more about how we use this patient’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 or call 0131 651 4114
* NHS Lothian : Lothian.DPO@nhs.net or call 0131 465 5444

**Future Studies**If this patient 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 this patient’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)

**Nominated Consultee Declaration form**

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

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

I confirm that I am the nominated consultee for

 ­­­­­­­­­­­­­­­­­ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of participant

------------------------------------------- -------------------------- -------------------

Name of nominated consultee Signature Date

----------------------------------------------- -------------------------- --------------------

Name of person undertaking consultation Signature Date

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