Study of the effectiveness and safety of treatments to help patients with anaemia recover from major emergency surgery. Perioperative Iron and ESA Intervention Study (POP-I)

IRAS ID: 1007432

Personal Legal Representative (PLR) Information Sheet

1. The person you are representing is invited to take part in our research study

- The POP-I study is looking at whether medications that treat anaemia (low blood count) can improve recovery and outcomes for older patients who are anaemic after having emergency surgery.
- This information sheet is to help you understand why the study is being carried out and what will happen if you decide the person you are representing would like to take part.
- We feel that the person you are representing is unable to decide for themselves whether to take part. To help decide if they should join the study, we would like to ask your opinion on whether or not they would want to be involved. We would ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about taking part in research. These should take precedence.
- Please take the time to read this information carefully and ask us if you would like more information or if there is anything that is not clear to you.
- If you are unsure about taking the role of legal representative, you may seek independent advice. We will understand if you do not want to take on this responsibility.
- It is entirely your decision whether you would like the person you are representing to take part in this study. If you agree for them to take part, you are free to withdraw them at any time without giving a reason.
- If you decide not to involve the person you are representing in the study, their care will continue in the normal way.
- If the person you are representing regains the capacity to consent before they are discharged from hospital, we will discuss the study with the person you are representing directly and let them decide if they would like to continue taking part in the study.

2. A summary of the study

Each year in the UK over 100,000 people aged 60 years or older are admitted to hospital for lifesaving emergency operations. Two of the most common emergency operations are for hip fracture and severe abdominal problems. Many of these people have anaemia (a low blood count)

after their surgery. Anaemia can increase the risk of complications after surgery and therefore anaemic patients can have a slower recovery after their operation.

Anaemia can be treated in several different ways. At the moment, we're not sure whether it's best to let anaemia get better on its own, or to give drugs that *could* speed up recovery. Normal hospital care does not usually involve any drugs to treat anaemia – just rest. Anaemia, especially if it's due to blood loss after an operation or injury, usually improves with time as the body naturally produces more red cells. If anaemia is severe then blood transfusions are sometimes used.

It is possible that helping the body correct the anaemia more quickly may allow people to recover faster, but we don't yet know whether giving drugs to do this will make a difference. This study will be looking at three treatment options to see which works best.

1. Usual hospital care. This doesn't involve any additional drugs for anaemia. This is the most common treatment for anaemia after surgery.

2. A single dose of iron, given through a drip. This is fairly common in hospitals but is not provided universally.

3. A single dose of iron, given through a drip, *plus* a single injection of a drug called an Erythropoiesis-Stimulating-Agent (ESA). An ESA works in combination with iron to increase the production of red blood cells and improve the blood count. The ESA we are using is called Darbepoetin. This is given less commonly to patients in hospitals with anaemia.

The aim of this study is to find out whether one *or* both of these treatments for anaemia can improve the outcomes for people who are anaemic following emergency surgery. It may be that normal hospital care is as effective as the other two treatment options. If that is the case, it may be possible to avoid giving unnecessary medicines to people.

Research on iron and ESA in other groups of patients, such as those with heart and kidney problems, has shown that the combination of these treatments work very well. However, we do not know whether they will help patients recovering from emergency surgery. This study will help to answer this question by measuring the effect of these treatments in 2400 patients who have anaemia after emergency surgery.

3. What is the purpose of the study?

The purpose of the study is to find out if the treatments for anaemia will help improve the recovery and quality-of-life for the person you are representing after their operation.

We are looking at two types of treatments that can increase their blood count.

1. A single dose of iron, which is given as an infusion into their vein
2. A single dose of an ESA (Darbepoetin), which is given as an injection under their skin.

Some patients in this study will only receive a single dose of iron, some will receive a single dose of iron *plus* a single dose of darbepoetin, and some will not receive either of these options (i.e. normal hospital care). All patients, regardless of whether or not they have received iron and/or darbepoetin, will receive the normal hospital care for patients with anaemia after an operation. This normal hospital care is guided by national guidelines and includes clinical observation and possible blood transfusion if required.

We will compare the two treatments for anaemia with normal hospital care to find out if the treatments help the person you are representing to recover quicker and go home earlier after their operation. We will measure their recovery by using some simple questionnaires we will send to you after they leave hospital.

If we find that these treatments improve recovery and quality-of-life, then we will be able to recommend that other patients receive them in the future to help them recover from emergency surgeries.

4. Why has the person I am representing been invited to take part?

We would like the person you are representing to be a participant in this study, because they have had emergency hip or abdominal surgery and they are aged 60 years old or over. Their blood count is lower than normal (anaemia) and the treatments that we are studying might help them to recover.

We are asking 2400 patients who have had an emergency surgery to take part in this research.

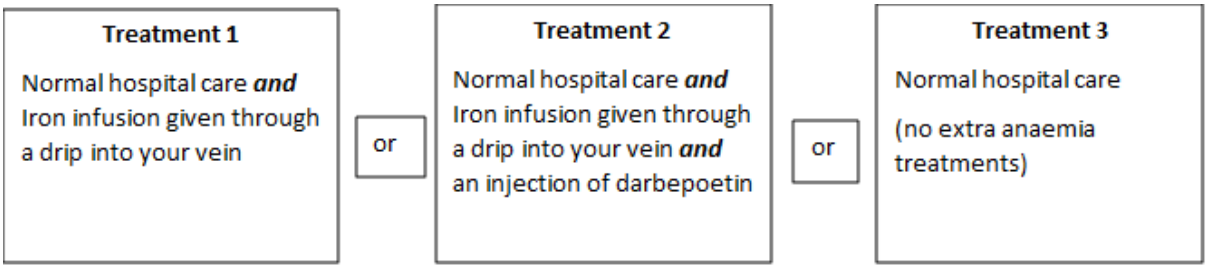
5. Does the person I am representing have to take part?

No. It is up to you to decide whether the person you are representing takes part in the study or not. A member of the research team will be able to answer any questions you might have. If you decide they should not take part, their care will continue in the normal way. If you decide they should take part, you are free to change your mind at any time and without giving a reason and this will not alter their care in any way.

6. What would taking part involve?

If you decide it is appropriate for the person you are representing to take part, we will ask you to complete a consent form on their behalf. After this, we will either take a blood sample or, if possible, use an existing blood sample, of the person you are representing. If we need to take a blood sample at this point, we will take approximately 3-5 teaspoons of blood by a qualified medical

professional. After this, we will allocate them to one of the three treatment options:



We will give the person you are representing the treatment for anaemia as soon as possible if they are allocated to either treatment 1 or 2. If allocated to treatment 1 or 2 then their blood pressure and pulse will be monitored before, during and after the administration of the treatment. We will also ask you to complete a short health-related questionnaire about them.

We would like to contact you after 30 days and 120 days to find out how the person you are representing is recovering and whether they have had to go back to hospital during this time. We will also ask you to answer the health-related questionnaire again. This can be done online using a link that we will send you by email or, alternatively, by telephone or by post. We may send you reminders to complete the questions if you do not complete them straight away to ensure we are able to collect data at the right time for the study

With your permission, we will inform the person you are representing's GP about their participation in this study. If you are unable to answer the health-related questionnaire because you do not have regular contact with the person you are representing then we may contact another person who has regular contact with the person you are representing. For example, a professional carer or a member of staff .

We will send a £15 shopping voucher when we send the 120-day questionnaire. This is to say thank you for your and the person you are representing's time, expertise, and involvement. We cannot offer any other payment to you or the person you are representing for taking part.

7. What are the possible benefits of taking part?

Taking part in the study may or may not directly benefit the person you are representing, but the information we collect from this study may help us to treat people with anaemia after emergency surgery in the future.

There is also a wider benefit to healthcare as a whole from taking part. If the research demonstrates that the iron or iron + ESA treatments are more effective than normal hospital care, then hospitals may begin offering these treatments to improve patient outcomes. Equally, if the research demonstrates that normal hospital care is as effective as any of the additional treatments, then the NHS may be able to save money, and put less treatment burden on patients, by *not* offering additional treatments for anaemia.

8. What are the possible disadvantages and risks of taking part?

The treatments that we are using are given to many other patients with different medical conditions in hospitals in the UK. We will monitor the safety of the person you are representing during and after the administration of the anaemia treatments and we will be looking at their medical notes to check for any other problems that might be associated with the treatments.

As with all injections or Intravenous administrations (a drip into the arm), the person you are representing may experience some short-term minor discomfort at the site where the injection or IV is given.

Intravenous (IV) iron has been associated with some side effects, most of which are very mild. The most common side-effects are:

- A strange taste for a short time.
- Low blood pressure, which can be treated.
- A raised temperature and shivering.
- Rashes and muscle aches.
- Skin reactions at or near injection site, including redness of the skin, swelling, burning, pain, bruising, discolouration, leakage to the tissue around the site of infusion, irritation.

Severe reactions to intravenous iron are very unusual.

ESA (Darbepoetin) has been associated with some side effects, most of which are very mild. The most common side-effects are:

- Mild allergic reactions.
- Rashes and swelling.
- Raised blood pressure.

Severe reactions to ESA (darbepoetin) are very unusual.

There is a small risk of blood clots associated with ESA. These may be more common in people with very impaired kidneys or with cancers. This risk is associated with repeated injections of darbepoetin over a longer time. In this study only one injection will be given. The research team in the hospital will check if your medical records for any known health conditions that put you at a high risk of developing a blood clot. If this is the case, then we will not include you in the study. If you have any concerns at all, you can discuss these during the consent process with the research team.

If the person you are representing has had an infection after their operation, we will wait until the doctors who are looking after them are happy that they are better before starting them in the study.

To read the Patient Information Leaflets (PIL's) for these medicines, (which includes a full list of known side effects), please request a copy from your local research team or access electronic versions from these links and QR codes:

Iron Patient Information Leaflet: www.medicines.org.uk/emc/product/5676/PIL

ESA (Darbepoetin) Patient Information Leaflet: www.medicines.org.uk/emc/product/7993/PIL

9. What if there is a problem?

If you have concerns or questions about any aspect of this study, you should ask to speak to the local researchers. Their contact details are at the end of this information sheet.

If any questions remain you can contact the study coordinating centre, Tel:07974 061 627, Email: POP-I@nottingham.ac.uk. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure via your local Patient Advisory and Liaison Service (PALS) <insert Local PALS details>.

In the event that something does go wrong and the person you are representing is harmed during the study, there are no special compensation arrangements. If they are harmed and this is due to someone's negligence then the person you are representing may have grounds for a legal action for compensation against the University of Nottingham but they may have to pay their legal costs. The normal NHS complaints mechanism will still be available to you and the one you represent.

10. What will happen if I don't want them to carry on with the study?

You are free to withdraw the person you are representing at any time, without giving any reason, and without their legal rights being affected. If you withdraw the person you are representing from the study, then the information collected will be kept and will still be used in the study analysis.

11. How will information about me and the person I am representing be used?

Researchers at the Nottingham Clinical Trials Unit (part of the University of Nottingham) will need to use information from you, the medical records of the person you are representing, and the local research team for this project.

This information will include the initials of the person you are representing their name and their NHS number (if in England or Wales), their CHI number (if in Scotland) or their H&C number (if in Northern

Ireland). This information will also include your name and contact details. The researchers will use this information to do the research or to check the records of the person you are representing to make sure that the research is being done properly. Your contact information will be used by the research team to contact you (via post, email or telephone) to complete study questionnaires, or to receive reminders to complete questionnaires, on behalf of the person you are representing and to share the findings from the study should you wish to receive them. If it is not possible to contact you to complete study questionnaires then we may contact another person who has close contact with the person you are representing, for example a home carer or staff at a nursing home.

People who do not need to know your, or the person you are representing's, identity will not be able to see your personal details, there will be a code number instead.

The researchers may also use information held by the person you are representing's GP, NHS Digital and other central UK NHS bodies to help provide information about their health status.
All information about you and the person you are representing will be kept safe and secure.

Once the study has finished, the data will be kept so the results can be checked and you can be told what happened in the study (unless you tell us you do not want to know). Reports will be written in a way so that no-one can work out that the person you are representing took part in the study.

12. What are your choices about how the information is used?

You can withdraw the person you are representing from the study at any time, without giving a reason, but we will keep information about them that we already have.

If you withdraw the person you are representing from the study, we would like to continue collecting information about their health from central NHS records. If you do not want this to happen, tell us and we will stop.

We need to manage our 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 the person you are representing.

After 7 years our data collected during the study will be disposed of securely.
If you give us your permission in the consent form, we may keep your contact details so we can get in touch if there is any relevant future research related to the condition of the person you are representing. You will also have the option to consent to the person you are representing taking part in future research using the data saved from this study. If you do not wish for your contact details to be kept for a copy of the study results to be sent to you or to be contacted about future research, these will also be disposed of securely at the end of the study.

If you provide a mobile telephone number to receive study information, then your name and telephone number will be held by Esendex (text messaging provider) and their subprocessors and will be used to contact you by text message. This information will be deleted by Esendex at the end of the study or after two years (whichever occurs first).

13. Where can I find about more about how the information is used?

You can find out more about how we use your information:

- at **www.hra.nhs.uk/information-about-patients/** and **www.hra.nhs.uk/patientdataandresearch**
- https://www.nottingham.ac.uk/utilities/privacy/privacy-information-for-research-participants.aspx
- at **http://www.nctu.ac.uk/data-protection/data-protection.aspx**
- by asking one of the research team
- by sending an email to POP-I@nottingham.ac.uk
- by calling the Nottingham Clinical Trials Unit on (0115) 823 1600

14. Who is organising and funding this study? How has it been approved?

The study is being organised by the University of Nottingham (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU). The funding for the study is provided by the National Institute for Health and Care Research. To protect your interests, all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given favourable opinion by London - Hampstead Research Ethics Committee.

Patients who have previously had an emergency laparotomy, or hip fracture surgery have helped us plan and design this study. Patients' representatives are also involved in the teams that oversee the running of the study.

15. What if relevant new information becomes available?

Sometimes we get new information about the treatment given to the person you are representing during the study. If this happens their research doctor will tell you about this new information and discuss whether they should continue in the study. If you decide it is not appropriate for them to carry on, the research doctor will make arrangements for care to continue as normal. If you decide it is appropriate for them to continue in the study, you may be asked to sign a new Informed Consent Form.

16. What will happen to any samples that are given?

The blood sample that we take for this study will be analysed at the local hospital laboratory and the results of the blood tests will be recorded by the research team. The sample will then be destroyed and no further tests will be performed on the blood sample. The results will be shared with the clinical team and the research team running the study.

17. What happens at the end of the study?

When the study ends, the healthcare of the person you are representing will continue as normal. If you decide to withdraw the person you are representing from the study, we will need to keep and use the data collected up to their withdrawal. At the end of the study the results will be published in scientific medical journals and presented at conferences. The person you are representing will not be identified in any publication. We will send you a newsletter with a summary of the study findings, unless you ask us not to.

We will send a £15 shopping voucher when we send the 120-day questionnaire. This is to say thank you for your and the person you are representing's time, expertise and involvement. We cannot offer any other payment for taking part.

Participants who are randomly assigned to receive a treatment will only receive treatment drugs once, at the start of the study. There will be no continued provision of the treatment drugs after the study has ended.

18. How to contact us

Contact details of your local research team;

- <insert contact details here>