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

Participant Information Sheet – Participant Regains Capacity

(For participants who have regained the capacity to consent to take part prior to discharge)

1. You are 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.
- Previously, a personal legal representative gave consent for you to take part in the study because, at the time, a medically qualified clinician deemed you were unable to consent for yourself. We did this because it is important to our research that we include all types of patients in this study, including those who were unable to consent to participate at the time.
- Now, you have regained the capacity to consent yourself to the study, it is up to you if you would like to continue taking part in the study. This information sheet is to help you understand why the research is being carried out and what it will involve for you if you decide to continue taking part.
- Please take 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.
- It is entirely your decision whether to continue to take part in this study. If you agree to continue to take part, you are free to withdraw at any time without giving a reason.
- If you choose not to continue to take part, your care will continue in the normal way.

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 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 your recovery and quality of life after the surgery that you have had.

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

1. A single dose of Iron, which is given as an infusion into your vein
2. A single dose of an ESA (Darbepoetin), which is given as an injection under your 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 you to recover quicker and go home earlier after your surgery. We will measure your recovery by using some simple questionnaires we will send to you after you 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 have I been invited to take part?

You have been invited to take part in this study because you have had emergency hip or abdominal surgery and you are aged 60 years or over. Your blood count is lower than normal (anaemia) and the treatments that we are studying might help you to recover.

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

5. Do I have to take part?

It is up to you whether or not you take part in the study. We will talk to you about the study and answer any questions you might have. If you agree to take part, we will ask you to sign a consent form. If you decide not to take part, you will continue to receive the usual care that your hospital provides.

6. What would taking part involve?

If you decide to continue taking part, we will ask you to sign a consent form.

After we received consent from a legal representative for you to take part, we either took a blood sample from you or, if possible, used an existing blood sample you had already provided as part of routine care. If we took a blood sample at this point, we would have taken approximately 3-5 teaspoons of blood by a qualified medical professional. After this, we randomly allocated you to one of the three treatment options:

Treatment 1	or	Treatment 2	or	Treatment 3
Normal hospital care ***and*** Iron infusion given through a drip into your vein		Normal hospital care ***and*** Iron infusion given through a drip into your vein ***and*** an injection of darbepoetin		Normal hospital care (no extra anaemia treatments)

It is very likely you have already been allocated to one of the three treatment options described above. Please ask a member of staff to find out whether you have received a study treatment or if you have been receiving normal hospital care and no additional treatments.

If you were allocated to treatment 1 or 2 then we gave you the treatment for anaemia as soon as possible. If allocated to treatment 1 or 2 then your blood pressure and pulse was monitored before, during and after the administration of the treatment. We also asked your legal representative to complete a short health-related questionnaire about you at this time.

We would like to contact you after 30 days and 120 days to find out how you are recovering and whether you have had to go back to hospital during this time. We will also ask you to answer the health-related questionnaire. 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 your GP, and your elected first point of contact about your participation in this study.

You will be sent a £15 shopping voucher when you are sent the 120-day questionnaire. This is to say thank you for your time, expertise and involvement. We cannot offer any other payment for taking part.

7. What are the possible benefits of taking part?

Taking part in the study may or may not directly benefit you, 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 your safety during and after the administration of the anaemia treatments and we will be looking at your medical notes to check for any other problems that might be associated with the treatments.

As with all injections or Intravenous (IV) administrations (a drip into your arm), you 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.

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 you have had an infection after your surgery, we will wait until the doctors who are looking after you are happy that you are better before starting you in the study.

To read the Patient Information Leaflets (PIL's) for these medicines, 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 you are harmed during the study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Nottingham, but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you.

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

You are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw the information collected will not be erased and may still be used in the study analysis.

You do not have any obligation to stay in the study, even though you have been previously enrolled on the study by a legal representative.

11.How will information about me be used?

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

This information will include your initials, name, contact number and your NHS number (if you are in England or Wales), CHI number (if you are in Scotland), or H&C number (if you are in Northern Ireland). The researchers will use this information to do the research or to check your records 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, to receive reminders to complete questionnaires, 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 you, for example a home carer or staff at a nursing home.

People who do not need to know your identity will not be able to see your name or contact details, your data will have a code number instead.

The researchers may also use information held by your GP, NHS Digital and other central UK NHS bodies to help contact you or provide information about your health status.

All information about you 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 you took part in the study.

12.What are my choices about how my 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 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.

After 7 years your data collected during the study will be disposed of securely. If you give us your permission, we may keep your contact details so we can get in touch if there is any relevant future research to do with your condition that you may be interested in taking part in. You will also have the option to take part in future research using your 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 my 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 NIHR HTA. All research in the NHS is looked at by an independent group of people, called a Research Ethics

Committee, to protect your interests. 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. Patient 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 your treatment during the study. If this happens your research doctor will tell you about this new information and discuss whether you should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue as normal. If you decide to continue in the study they may ask you to sign a new Informed Consent Form.

16.What will happen to any samples I give?

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, your healthcare will continue as normal. If you withdraw from the study, we will need to keep and use the data collected up to your withdrawal. At the end of the study the results will be published in scientific medical journals and presented at conferences. You 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.

You will be sent a £15 shopping voucher when you are sent the 120-day questionnaire. This is to say thank you for your 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>