Participant Information Sheet

ANAEMIA MANAGEMENT WITH RED BLOOD CELL TRANSFUSION TO IMPROVE POST-INTENSIVE CARE DISABILITY ('ABC post-intensive care trial')

You are being invited to take part in a research study. You are eligible to take part because you have been treated in an intensive care unit (ICU) and blood tests show that you are anaemic (have a low level of haemoglobin in your red blood cells). Before you decide whether or not 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 or not you wish to take part.

Thank you for your time

What is the purpose of the study?

The purpose of this study is to find out if we can improve the health of ICU patients by treating their anaemia with blood transfusions from the time they leave ICU. We aim to recruit 346 patients to the trial from around 20 to 25 Intensive Care Units (ICUs).

You have spent time in ICU and routine blood tests show that you are anaemic (a low level of haemoglobin, which attaches to and carries oxygen in the blood). Anaemia is the result of either not having enough red blood cells containing haemoglobin to take oxygen around the body, or faulty red blood cells that are unable to carry enough oxygen. Anaemia is very common in patients who have received intensive care treatment and can occur for several reasons. Bleeding can make people anaemic as can the blood sampling necessary for routine tests in the ICU. Severe illnesses also prevent new red blood cells (RBCs) being produced in the bone marrow, probably because inflammation in the body stops the bone marrow working correctly.

The main way we treat anaemia is by giving people a blood transfusion, which can increase the haemoglobin level in the RBCs. When patients are in ICU they can tolerate being anaemic quite well so we try not to give blood transfusions unless haemoglobin levels are very low. However, many patients are severely anaemic when they leave ICU and we know that it can take many months for their anaemia to recover.

After discharge from ICU it is common for patients to feel tired and fatigued. Tiredness and fatigue are typical signs of anaemia. Regaining energy and health after being in ICU can take a long time and impact on many areas of life. Currently we don't know if treating anaemia can improve energy levels and recovery after ICU. We do know treating anaemia can improve health for patients in other situations. Before recommending this for post-ICU patients, we need to be sure that giving blood transfusions really benefits these patients too because blood is in short supply and transfusions can have complications.

We want to find out if treating anaemia with blood transfusions can improve energy levels and recovery after ICU.

Do I have to take part?

No. It is up to you to decide whether or not you want 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 still free to change your mind **at any time** without giving a reason.

Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive now or at any stage in the future.

What will happen if I take part?

If you agree to take part in the study, we will use a computer to randomly decide which of two different approaches to treating anaemia with blood transfusions will be used while you remain in hospital. When patients leave ICU the current approach is not to actively treat anaemia (current standard care). After starting on the study one group will continue with this standard care. The other group will receive a more liberal approach to blood transfusion, where anaemia will be more actively treated with blood transfusion(s).

The two groups are detailed below:

Standard care group	Intervention group
Patients will receive blood transfusions as per current standard care to treat their anaemia and allow their red blood cell count to be at a lower level (Haemoglobin level 70 to 90 g/L)	Patients will receive more blood transfusions to treat their anaemia and keep their red blood cell count at a higher level (Haemoglobin level 100 to 120 g/L)

You will be in one of the above two groups after leaving ICU and will remain in that group until you are discharged from hospital.

All patients in the study will have their blood tested to check the haemoglobin level at least once a week while they are in hospital and after receiving any blood transfusion. This blood test is part of routine care while patients are in hospital. In addition to these routine blood tests, with your permission, we will take a 20 ml blood sample (about 3 teaspoons full) at the start of the study to identify which patients could benefit most from blood transfusions. These samples will be analysed by our collaborators at the University of Oxford. The details included with the samples will not include identifiable information.

Samples will be labelled with a unique study number and only the local site and the trial management team will have access to the identifiable data. The trial management group will require your identifiable data for the purposes of follow up.

All other aspects of care during the hospital stay will be decided by the doctors and nurses looking after you. Your care will not be affected by you being in the study.

We will follow you up three times after joining the study, at 1 month, 3 months and 6 months.

1 month:

At 1 month, if initial sample taken at baseline (at time of entry into the study), we will take a 20 ml blood sample (about 3 teaspoons full) to check your haemoglobin level and identify which patients benefit most from blood transfusions. Again these samples will be analysed by our collaborators at the University of Oxford. We will also ask you to complete some questionnaires which will ask about

- your quality of life,
- symptoms of fatigue,
- your ability to carry out daily tasks,
- your health service use and any expenses you have had as a result of your health.

The questionnaires will take around 30 minutes to complete. You will be invited into the hospital for this follow up visit and we will cover reasonable travel expenses, however if you are unable to manage, a member of the research team from the hospital will visit you at home.

3 and 6 months:

The follow up at 3 and 6 months will only involve completing questionnaires - similar to the ones used at the 1 month follow up visit. You will be offered different options for completing and returning these questionnaires, which will be organised by the research team. You can decide to complete the questionnaires by post, by phone with a member of the research team or alternatively online using a link provided by the research team. There is no requirement for you to come back to the hospital for these 2 later visits.

We may also use blood samples and data collected to answer other important questions if ethical approval is given for these additional studies.

What are the possible benefits of taking part?

Taking part in this study may help to improve outcomes for patients who are anaemic following a stay in ICU in the future. There are no direct benefits to you from taking part in the trial.

What are the possible disadvantages of taking part?

We are doing this study to find out whether it is better to receive more blood transfusions to treat anaemia after leaving intensive care than is current standard care. Although blood transfusions are safe, they do carry some risks. These can include transfusion reactions which can occur after up to one in a hundred transfusions. Transfusion reactions are usually mild (for example a fever or rash) but very rarely can be severe. Other complications include breathing problems and infections, although these are very rare. We will be closely monitoring what happens to patients in both groups to make sure that we find out about any problems quickly and treat them appropriately.

What if there are any problems?

If you have a concern about any aspect of this study please contact <enter contact name for local research team>, telephone <enter contact number>, who will do his/ her best to answer your questions.

In the unlikely event that something goes wrong and 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 (site details to be added) but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you and won't be affected by agreeing to take part in the study.

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. If you choose to withdraw from the trial, we will ask you to complete a withdrawal form. On the form you will have 3 options for your withdrawal:

- First, whether you would be happy for us to follow you up and collect information about how you are from your medical records and, if you choose, by contacting you to undertake questionnaires and possibly blood samples. Even though you decided to stop participating in one of the two blood transfusion groups, the information you provide will be very useful in the trial and help us answer the research questions we have.
- Second, you may decide that you want to stop being involved in the trial any more, and not have any further data collected in the future, but are happy that we can use the data we have collected so far.
- Third, you may decide to withdraw from all aspects of the trial and follow up, and ask for all of the research data collected to be removed and not included in the study analysis.

What happens when the study is finished?

You will be active in the study until you have completed your 6 month follow up. Follow up over a longer period is expected to take up to 5 years and will be completed from routinely collected information, which will not require you to be contacted. We plan to publish the results shortly after all the long term follow ups have been completed, through medical publications, websites, and press releases, but individual patients will not be identifiable in any published results.

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 patients' privacy at every stage.

We will write to your General Practitioner to let them know that you have agreed to take part in the study.

All information and samples will be stored by the University of Edinburgh and 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 responsible 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 (patients in Scotland only) or your 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.

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.

• 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.

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/

• our leaflet available from www.hra.nhs.uk/patientdataandresearch

• by asking one of the research team

• by sending an email to the ABC.Trial@ed.ac.uk email address, or the Data Protection Officer: Rena.Gertz@ed.ac.uk

• by ringing us on 0131 651 9923

Who is organising and funding the research?

This study has been sponsored by the University of Edinburgh and NHS Lothian. It is funded by the JP Moulton Foundation.

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 [XXXX] Research Ethics Committee. NHS Management Approval has also been given. Previous ICU patients and relatives 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>.

Further information regarding the study is available via the QR code below and on the study website at https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/all-current-studies/abc

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact:

Professor Michael Gillies
Consultant Critical Care Royal Infirmary of Edinburgh
Honorary Professor, School of Clinical Sciences, University of Edinburgh
Tel: 0131 242 3314

Complaints

If you wish to make a complaint about the study please contact:

<insert contact details> to be adapted depending on research site.

Participant ID:		Centre ID (if applicable)	

CONSENT FORM
Participant

ANAEMIA MANAGEMENT WITH RED BLOOD CELL TRANSFUSION TO IMPROVE POST-INTENSIVE CARE DISABILITY ('ABC post-intensive care trial')

		Please Initial Boxes
1.	I confirm that I have read and understand the information sheet (VERSION DD MM YYYY) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.	☐
2.	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.	☐
3.	I give permission for the research team to access my medical records for the purposes of this research study.	☐
4.	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.	☐
5.	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 Edinburgh Clinical Trials Unit for administration of the study.	☐
6.	I give permission for my Community Health Index (CHI) number/hospital number to be collected and passed to the University of Edinburgh and the Edinburgh Clinical Trials Unit.	☐
7.	I agree that the information held and maintained by NHS Digital, NHS National Services Scotland, ISD (Information Services Division, Scotland) and other central UK NHS Bodies may be used to provide information about my health status.	☐
8.	I agree to my General Practitioner being informed of my participation in this study.	☐

Participant ID:		Centre ID (if applicable)	

9.	I understand that data collected about me during the study may be converted to anonymised data.		☐
10.	I agree to provide a blood sample at the start of the study and another at 30 days as part of the research study.	Yes ☐	No ☐
11.	I agree to my identifiable data and/ or blood samples being used for future ethically approved studies.	Yes ☐	No ☐
12.	I agree to my anonymised data and/ or blood samples being used in future studies.	Yes ☐	No ☐
13.	I agree to take part in the above study		☐

Name of Person Giving Consent	Date	Signature
Name of person receiving consent	Date	Signature

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