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Patient Information Sheet

Title of Study: A Multi-Centre Randomised Controlled Trial of Pre-Hospital Whole Blood Administration versus Standard Blood Component Care for Traumatic Haemorrhage.

Chief Investigators: Dr Laura Green and Professor Jason Smith

Sponsor: NHS Blood and Transplant (NHSBT)

Introduction

This hospital is taking part in a research study to investigate different types of blood transfusion given to patients who are bleeding after suffering a serious injury.

Why have I been invited to take part?

You recently suffered from a severe injury and major bleeding. As part of your emergency care in the air ambulance (before you arrived at the hospital), you needed a blood transfusion. The doctors and paramedics treating you agreed that it was appropriate for you to enter a research study investigating treatments for bleeding in patients with severe injuries. This decision was made by your doctors on your behalf, as you were too unwell to consider taking part at that time. Now that your condition has improved, we would like to give you more information about the study and ask whether you would consider continuing in the study.

This research will help us improve the care of patients who suffer severe injuries in the future. Before you decide whether or not to continue in the study, it is important for you to understand why it is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information.

If you decide that you do not wish to continue in the study, it will not affect the standard of care you receive in any way.

What is the purpose of this study?

This study is investigating different blood transfusion treatments for patients with severe bleeding before they get to hospital. Every year, uncontrolled bleeding due to

major injury accounts for more than 2 million deaths worldwide and 4,500 deaths in England.

Blood transfusion is an essential part of the treatment for severe bleeding, and any delay to starting transfusion can reduce the chances of survival. In the UK patients are often transfused blood at the scene of an incident, before they arrive at hospital. Transfusion may involve different blood components, red blood cells (important for carrying oxygen around the body), plasma (contains essential proteins to help blood clot) and platelets (small cells that are essential for blood clot formation).

Most UK air ambulances treat bleeding patients with a combination of red blood cells and plasma, which come in separate bags. Platelets are stored differently to other products and are more difficult to carry on air ambulances, so are only given after arrival at hospital.

However, carrying separate blood component bags introduces logistical challenges due to the additional weight the team needs to carry; increased complexity as several bags may need to be given to each patient; and a potential delay in transferring patients to hospital. Whole blood contains red cells, plasma and platelets all in one bag, as taken from a blood donor. Giving a blood transfusion of all of the components in a single bag could overcome these challenges.

In this study, one group of patients will be given transfusions of red blood cells and plasma. The other group of patients will receive transfusions of whole blood. The effects of the two different treatments will be compared by looking at survival in the two groups and the amount of blood needed over the first 24 hours after injury. We are also investigating how you are doing up to three months after your injury.

At the end of the study we will determine which of the transfusion types is better (or whether there is no difference between them) so that more patients in the future will get the best treatment.

What will happen if I agree to continue to take part?

If you agree to continue to take part in the study, we are asking for your consent to:

- Allow us to collect routine clinical information about you, the care you receive while you are in hospital and after you are discharged.
- Be contacted and complete a questionnaire about your health three months after your injury.
- For us to contact your GP to find out about your health in three months' time, if we cannot contact you.

We are also asking for your consent to use your identifiable information to obtain more detailed medical information following your injury from different organisations. These organisations are the Trauma Audit and Research Network (TARN) and the Intensive Care National Audit & Research Centre (ICNARC). They collect complex data from patients across the country. We will need to collect data from them about your injuries and care. Your information will be stored securely on NHS computers by NHS Blood and Transplant, protected by password and only accessible by the research team. At the end of this study, all identifiable data stored will be destroyed.

What are the possible risks and benefits of taking part?

There are no known risks linked to/attributed to taking part in this study, and there are no known additional risks in participating in the study compared to the risk associated with transfusing blood components.

However, information collected as part of your participation in this trial may benefit patients in the future, even if you were randomly allocated to the standard treatment group.

What if there is a problem?

If you have any concerns about any aspect of this study, you should ask to speak to the researchers who will do their best to answer any questions. If you remain unhappy and wish to complain formally, or if you wish to speak to someone who is independent of this study please contact your local hospital Patient Advice and Liaison Service (PALS). You can speak to them on the telephone [local Trust PALS number here], via email at [local Trust PALS email here] or ask them for an appointment in person.

In the unlikely event that something does go wrong and you are harmed during the research due to negligence then you may have grounds for a legal action for compensation against the NHS Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

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

It is up to you to decide whether to take part in the study or not. If you decide to continue to take part you will be free to change your mind at any time, without giving a reason. If you did decide to withdraw from the study it will not affect the care you receive now or at any time in the future. If you agree to continue to take part in this study, you will be given this information sheet to keep and will be asked to sign a consent form. If you do withdraw from the study, we will keep the data we have collected up to your withdrawal. We would like to continue collecting information about your health from your hospital records and from central NHS records. If you do not want this to happen, tell us and we will stop.

How will my information be used?

We will need to use information from your medical records for this study. This information will include your NHS number and date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly.

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

We will keep all information about you 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 you took part in the study.

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. We will ask whether you agree for us to keep the data that has been collected so far.
- 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 informationgovernanceteam@nhsbt.nhs.uk

Will my GP be informed of my participation in the study?

Yes, we will write to your General Practitioner to inform them that you are taking part. If we think that you show signs of extreme anxiety and depression during the study, we will contact your General Practitioner to let them know.

What will happen to the results of the study?

Once the study is completed the results will be published in scientific and medical journals and presented at meetings. We will also provide a summary of the results on a dedicated study website which can be accessed at: www.nhsbt.nhs.uk/SWIFT. You will not be identifiable in any publications or presentations resulting from this study.

Who is organising the research?

The study is being managed by NHS Blood and Transplant Clinical Trials Unit. The study has been funded by NHS Blood and Transplant, the Ministry of Defence and ten different Air Ambulance Services.

Who has reviewed the study?

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 approved by the South Central – Oxford C Research Ethics Committee and the Health Research Authority.

The information sheets for the study (like this one that you're reading) have also been reviewed by members of NHS Blood and Transplant's Patient and Public Advisory Group.

Who should I contact for further information?

If at any time during the study you have questions or concerns regarding the study you can contact the local Principal Investigator or Research Nurse, who is in charge of the research study at your hospital:

Principal Investigator	Research Nurse
[to be localised]	[to be localised]