acrobat!

administering cryoprecipitate in obstetric bleeding at an earlier time

PARTICIPANT INFORMATION SHEET

Title of Study: The effect of early cryoprecipitate transfusion versus standard care in women who develop severe postpartum haemorrhage: A pilot cluster randomised trial (ACROBAT: Administering CRyoprecipitate in Obstetric Bleeding At an earlier Time)

Chief Investigator: Dr Laura Green
Sponsor: Queen Mary University of London

Queen Mary University of London

Barts Health NHS Trust

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NHS Homerton University Hospital NHS Foundation Trust

BARC BARTS RESEARCH CENTRE FOR WOMEN'S HEALTH

SECTION 1: Why am I being given this leaflet?

Introduction

This hospital is taking part in a research study to investigate the treatment for Postpartum Haemorrhage (PPH), a condition where there is heavy bleeding in pregnant women after childbirth, requiring blood transfusion.

This research will help us understand how best to improve the care of women who suffer heavy bleeding during childbirth in the future. Before you decide, it is important for you to understand why the research is being done and what it involves. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information.

Why have I been invited to take part?

You experienced heavy bleeding during or after childbirth, which required emergency treatment with blood transfusion. This hospital is taking part in a research study called ACROBAT. In this study, some of the participating hospitals have had a change to the order in which standard blood products are given during emergency blood transfusion. This is a change that is of very low risk.

At the time of the bleeding, it was not appropriate to discuss this with you, as the priority was to deliver treatment, rather than introduce any delays that could have potentially affected your care.

We now would like to ask you if you would consider continuing in this study and allow us to collect information about your health. Participation in this study is completely voluntary. You will be given this information sheet to keep. If you agree to continue to take part in this study, you will be asked to sign a consent form.

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

If you agree to continue to participate in the study we are asking for your consent for the following:

- To collect routine clinical information about you and the care you received when you experienced heavy blood loss.
- We would ask you to complete a short one-page questionnaire about your health and wellbeing.

- To analyse any leftover blood from routine samples that may have already been taken as part of managing your bleeding (no additional blood tests will be required).

- We would like to contact you by telephone 3 months after you leave the hospital, to ask about your health status. If we cannot reach you, we would like to contact your GP for this information.

Regarding the blood samples, we will only use the leftover blood from samples taken during your delivery and time in hospital. These blood samples are taken as part of routine care. The blood will be analysed in a central laboratory, to better understand how we can improve management of PPH. We will not perform any genetic testing on these samples. Blood samples will be destroyed once the study has ended.

Finally, we are inviting a small number of women to take part in a 1-hour interview about their views and experiences. This is so we can find out how women feel about being included in this study and learn how to best plan a future large-scale trial. The researcher conducting these interviews may be male or female, will be from Queen Mary University of London and the interviews will take place after discharge from hospital. You do not have to take part in this interview if you don't want to. It is still possible to take part in this study without having the interview. If you'd rather not be contacted about this, you can let a member of the research team know.

SECTION 2: More information about why the ACROBAT study is needed

What is Postpartum Haemorrhage, and what is the current standard treatment?

Healthcare in pregnancy and during labour in the UK is one of the best in the world, and most women experience no significant problems. However, despite medical treatment, some women may experience heavy bleeding during and up to 24 hours after labour. This bleeding is called postpartum haemorrhage (PPH).

PPH is rare, and the majority of women recover from it without needing any blood products. However, in some instances (2%), heavy bleeding can be so severe and potentially life-threatening that treatment with blood products is necessary. In this case, a standard

protocol is followed by doctors to allow for transfusion of different blood products, which are normally given in a particular order: at first, **red blood cells** and **fresh frozen plasma** are given, and if bleeding does not stop, **platelets** and **cryoprecipitate** are given at a later point. We don't currently have very good evidence if this is really the best order to give blood products in order to stop further bleeding. Cryoprecipitate is usually given later on, or in some cases it may not be given at all, because it is a limited resource.

What is Cryoprecipitate?

Cryoprecipitate is a blood product that has been separated from the whole blood donation and frozen. If needed, cryoprecipitate is thawed and then given to patients as a transfusion. Cryoprecipitate has been used in the UK for over 40 years for treatment of bleeding, including during childbirth, and is very safe.

Cryoprecipitate is very rich in a protein called fibrinogen. Fibrinogen plays an important role in the formation of a blood clot and so helps to stop the bleeding. During PPH fibrinogen is lost quite early in the course of bleeding, and therefore replacing it early – by giving cryoprecipitate earlier – could improve outcomes for women who experience heavy bleeding, as bleeding may be stopped more rapidly.

What is the purpose of the ACROBAT study?

In the ACROBAT study, we are trying to find out if giving cryoprecipitate earlier – at the same time as red blood cells – could stop bleeding more quickly.

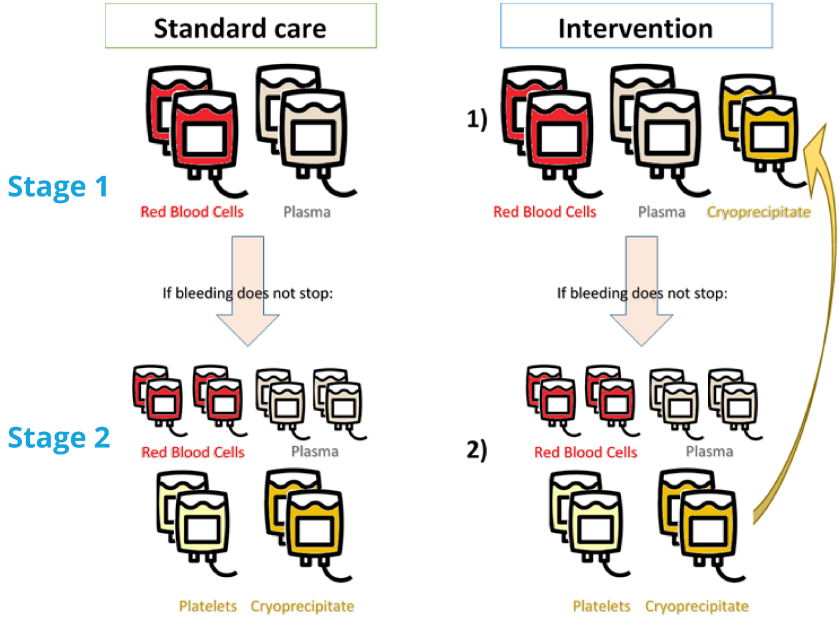
In order to prove this, we would need to perform a large trial, which would require significant resources and a large number of women to participate. Before we run such a large trial, we need to test whether it is feasible to deliver the trial, and the ACROBAT study is aiming to do just that – this is why it is called a pilot study. The ACROBAT study will assess if cryoprecipitate can be administered within 90 minutes of the onset of bleeding, as well as collect information on clinical outcomes of women participating in the study. We will also collect information on how to fine tune study processes and find out what women and healthcare professionals think about the way we run the study.

How is the ACROBAT study designed?

We plan to recruit 200 patients across 4 hospitals in the UK. In the study, hospitals are randomly allocated into 2 groups: 1) standard care group and 2) intervention group.

- **Standard care group**: all women who deliver in these hospitals and who develop severe bleeding that requires blood transfusion receive exactly the same treatment as usual. This means that cryoprecipitate is given later in the course of bleeding, and in some cases may not be given at all.

- **Intervention group**: all women who deliver in these hospitals and who develop severe bleeding that requires blood transfusion, receive cryoprecipitate early, in addition to standard treatment. All other aspects of the management of PPH will remain exactly the same – women still receive the same amount of red blood cells and plasma as in the standard, and further cryoprecipitate transfusion can still be given at a later stage if required.



This type of research is called a **cluster-randomised trial**. We are doing this because in the intervention group, the healthcare teams have changed the way they treat all women who need transfusion. This is done so we get the most reliable and clear-cut study results possible.

If you would like to know which group your hospital is in, you can ask the person obtaining consent from you, your doctor, research practitioner, nurse or midwife.

SECTION 3: Information about my participation

How have I been identified?

A member of the research team has looked through the medical records to identify women who have experienced heavy bleeding after childbirth and received a transfusion of blood products.

What are the possible benefits of taking part?

There is no guarantee that you benefit directly from participation in this study. Participants receiving early cryoprecipitate might respond better, but at present we do not know if this will be the case. The information we get from this study will help us improve and develop future studies. It may also help us to improve the treatment of pregnant women who experience PPH during childbirth in the future.

What are the possible disadvantages and risks of taking part?

We do not expect there to be any disadvantages for you by being included in this study, because cryoprecipitate is already part of standard care, and we are only proposing to give it early rather than later on in the course of bleeding. Cryoprecipitate is not a new drug or product; it has been used safely in the UK for over 40 years.

What if there is a problem?

If you have any concerns about any aspect of this study, you should ask to speak to the research team 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 from this study, please contact your local hospital Patient Advice and Liaison Service (PALS) – see below for contact details.

We do not believe that any harm will come to you through taking part in this trial. The organisers of the study do however have insurance in place for any injury caused as a direct result of the intervention or procedures you received during the course of the study.

Do I have to take part, and what happens if I change my mind?

It is up to you to decide whether to take part in the research or not. If you decide to continue you will be free to change your mind at any time, without giving a reason, and then we won't collect any further data for this study. If you would like us not to collect routine data from your medical records, you are also free to opt out. This will not affect the quality of care you receive now or at any time in the future.

Will my taking part in the study be kept confidential?

Your hospital routinely collects information about you in your medical records. We will access this information, with your permission, for this research study. Your

hospital will keep a record of your name, date of birth, NHS number and contact details confidential and will not pass this information to the study organisers. Your hospital will use this information as needed for your care, to contact you about the research study, and make sure that relevant information about the study is recorded to oversee the quality of the study. Certain individuals from the study organisers and regulatory organisations may look at your medical and research records to check the accuracy of the research study. All information collected about you during the course of the research will be kept strictly confidential and will be stored securely. The study organiser (Queen Mary University of London) will only receive data about you that contains no identifying information (no names, dates of birth or NHS number), only a unique study number. If shared with other researchers, your data will be completely anonymised.

Your hospital will keep identifiable information about you from this study for 20 years after the study has finished. Any leftover blood samples will be destroyed at the end of the study.

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

Yes, with your permission, we will write to your general practitioner/ family doctor to tell him/her about the study and inform him/her that you are taking part.

Who is organising and funding the research?

The study is funded by Barts Charity. Queen Mary University of London is the sponsor for this study based in the UK. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Queen Mary University of London will keep information about you for 20 years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will not collect any further data about you, but we will keep the information about you that we have already obtained. You can find out more about how we use your information at www.jrmo.org.uk.

How have patients and the public been involved in this study?

Members of our patient and public group called Katie's Team have provided input into the research proposal, the process of recruiting participants and the patient documents, and will continue to support the progress of this study.

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What happens 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 of health professionals. We will also provide a summary of the results on a dedicated ACROBAT website. You will not be identified in any publications or presentations resulting from this study.

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 reviewed and given favourable opinion by the **London - Brighton & Sussex Research Ethics Committee** (Reference Number **18/LO/2062**)

What happens to the results of the study?

If at any time during the study you have questions or concerns regarding the study, you can contact the local principal investigator or research midwife who are responsible for the study at your hospital:

Principal Investigator name/contact details:

Research midwife name/contact details:

Patient Advice and Liaison Service (PALS):

Thank you for taking the time to read this information leaflet.

Queen Mary University of London

Barts Health NHS Trust

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