What this means for you

We want to make sure all women and their partners have an opportunity to find out more about the ACROBAT study, and how it may affect them.

98% of women will not need any transfusion – in this case, this study will not affect you at all. If you do have bleeding after childbirth which requires a blood transfusion, you will be treated according to the group your hospital is in. Your doctor, midwife, or study team member will speak to you more about the study and ask for your consent to collect additional data about your health, to help us answer our research questions. You will be free to refuse your consent for this.

What are the risks?

We do not expect there to be any risks for you by taking part in this study, because cryoprecipitate is already part of standard care, and we are only proposing to give it at an earlier time. Cryoprecipitate is not a new drug or product and has been used safely in the UK for over 40 years.

Why is this study important?

Bleeding after childbirth that requires blood transfusion is a major and serious health problem globally.

This research will help improve the care of women who suffer from severe bleeding during childbirth in the future.

Any Questions?

If you would like to know more or have any questions please contact us - you can ask to speak to one of our study team or visit our website, where you can download the full Patient Information Sheet.

Phone:

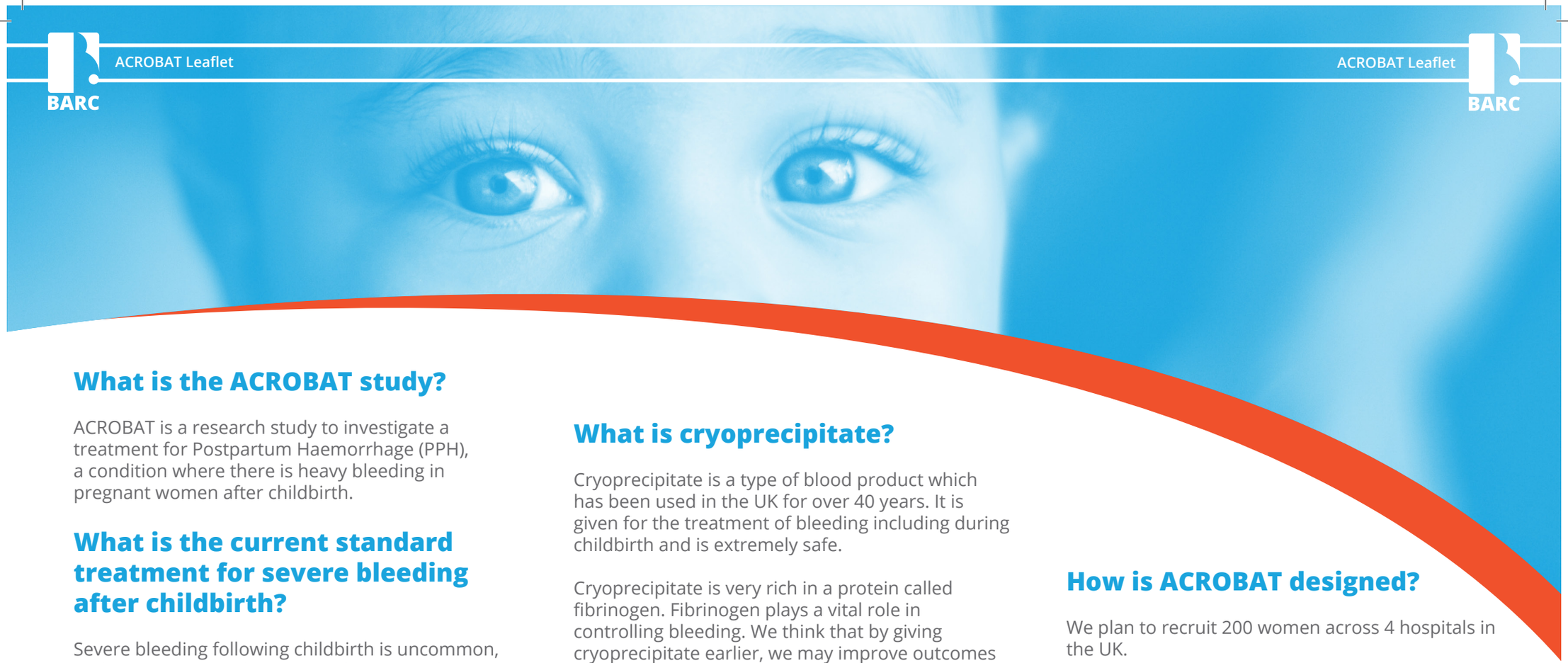
Website:

Queen Mary University of London · Barts Health NHS Trust · b+tlc Barts Charity · NHS Homerton University Hospital NHS Foundation Trust · BARC

THIS HOSPITAL IS TAKING PART IN THE acrobat ! STUDY

ADMINISTERING CRYOPRECIPITATE IN OBSTETRIC BLEEDING AT AN EARLIER TIME

Queen Mary University of London · Barts Health NHS Trust · b+tlc Barts Charity · NHS Homerton University Hospital NHS Foundation Trust · BARC



What is the ACROBAT study?

ACROBAT is a research study to investigate a treatment for Postpartum Haemorrhage (PPH), a condition where there is heavy bleeding in pregnant women after childbirth.

What is the current standard treatment for severe bleeding after childbirth?

Severe bleeding following childbirth is uncommon, and most cases can be managed using medication to control bleeding. However, in rare cases (2 in 100 deliveries), the bleeding can be so severe that blood transfusion treatment is required to stop the bleeding. In such cases, a standard protocol is followed by doctors to give different blood products which are normally given in a particular order:

1. At first, Red Blood Cells and Fresh Frozen plasma are given.

2. IF bleeding doesn't stop, platelets and cryoprecipitate are given.

We don't currently have very good evidence if this is really the best order to give blood products in PPH.

ACROBAT Leaflet

What is cryoprecipitate?

Cryoprecipitate is a type of blood product which has been used in the UK for over 40 years. It is given for the treatment of bleeding including during childbirth and is extremely safe.

Cryoprecipitate is very rich in a protein called fibrinogen. Fibrinogen plays a vital role in controlling bleeding. We think that by giving cryoprecipitate earlier, we may improve outcomes for women with PPH.

Why are we running the ACROBAT study?

In the ACROBAT study – we are proposing to give cryoprecipitate earlier – at the same time as the first two units of red blood cells.

We believe this will improve fibrinogen levels and may potentially stop bleeding more quickly.

The ACROBAT study is a pilot study, to test whether it would be feasible to deliver cryoprecipitate early – within 90 minutes – which is essential before performing a large study in the future.

ACROBAT Leaflet

How is ACROBAT designed?

We plan to recruit 200 women across 4 hospitals in the UK.

In the study, hospitals will be randomly allocated into 2 groups:

1) Standard care group
In this group, nothing changes. Blood transfusion will be given exactly the same as normal. This means cryoprecipitate will be given later in the course of bleeding if necessary.

2) Intervention group
In hospitals allocated to this group, cryoprecipitate will be administered early instead of later. All other treatments will remain the same.

This type of study is called a CLUSTER-RANDOMISED STUDY.