[HOSPITAL CONTACT DETAILS]
Name of PI
Name of Hospital
Hospital address
Contact phone number

A randomised controlled trial to assess the pharmacokinetics and pharmacodynamics of intramuscular, intravenous and oral administration of tranexamic acid in women giving birth by caesarean section

STUDY INFORMATION FOR PARTICIPANTS

We invite you to take part in a research study called WOMAN-PharmacoTXA

- Before you decide to take part or not, we would like you to know why the study is being done and what it will involve.
- Please read this information. You can talk to others about the study if you wish.
- You can ask the doctor or midwife looking after you as many questions about the study as you like before deciding to take part or not.
- It is up to you to decide to take part in this study or not. If you choose not to take part, your doctors and midwives will give you the usual care given at this hospital.

Contents

1. What is the study for?

Some women experience heavy bleeding during and after having a caesarean section (C- section) birth. We already know that giving a drug called tranexamic acid or TXA into the vein of women who develop heavy bleeding after childbirth can save their lives. However, the treatment has to be given really early and no later than 3 hours after giving birth. It would be better if we could stop women from having a large bleed in the first place. We want to find out if giving tranexamic acid to women who are having a C-section stops them from bleeding too much, especially those women who are at risk of having a large bleed.

We also want to know which way of giving TXA works. Usually TXA is given by injection in the vein, this needs to be done by a qualified medical person who may not be available especially when women give birth at home or in small clinics.

TXA can also be given as an injection into muscles or as a drink, these ways of giving the drug may be easier and quicker. Our aim is to see if giving TXA in a drink or by injecting in the muscle can be absorbed by the body and work as well as when it is given in the vein, this information will help women at risk of bleeding in the future.

2. Why are you asking me to take part?

We are asking you to take part because you are expected to give birth by a caesarean section and you are at a high risk of heavy bleeding afterwards.

We are giving this information to you and asking you to take part. If you agree the study team at this hospital can include you in the study.

You will not be able to take part if:

- You are less than 18 years old
- You will be giving birth vaginally
- Your C-section has to be done urgently (less than 1 hour after your admission to hospital).
- You are allergic to the study drug
- You develop severe bleeding before the caesarean section
- You have received tranexamic acid within 48 before the caesarean section
- Your kidneys are not functioning properly
- You have any medical condition which makes you bleed a lot

About 120 women will be taking part in this study. It is up to you to decide if you wish to take part or not.

3. What will happen if I take part?

Taking part in the study will not change the usual care given to women having a C-section at your hospital.

- We will ask you to fill in a form to say that you are willing to take part.
- We will ask you some questions about your health, measure your height and weight, take your blood pressure, heart rate and your breathing rate.
- We will take a small sample of blood from your vein to do a blood test to tell us about your blood clotting, how well your kidneys are working and if you are anaemic or not. This will be

taken from the needle which is put into your vein to prepare you for surgery so there will be no extra needles for this.

- About one hour before your C-Section we will do a small finger prick blood test.

We will then choose one of four ways to treat you. The treatment you will get is decided is by a computer and the doctors cannot change this. They will not know in advance what you will receive. Each person has an equal chance of receiving any one of the following:

1. an injection of tranexamic acid in a vein
2. two injections of tranexamic acid in different muscles
3. tranexamic acid in a drink
4. no tranexamic acid.

We will then repeat the finger prick blood tests and blood samples from the needle in your vein. We will also check your blood pressure, heart rate and breathing rate, how much blood you have lost and if you have any problems from the treatment. We will record the checks which are done on all babies at birth called the APGAR score. Immediately after the birth of your baby, once the umbilical cord is clamped, we will collect a small blood from the umbilical cord. All babies have a routine blood test done soon after birth using a small prick on the heel. At the same time this is done, we will take a small blood sample from your baby. We will also check you and your baby for any medical problems while you are in hospital. Also, if you received your treatment by injection into your muscles, we will check for any pain, bruising or any other problems.
You can see in the table below how often we will need carry out these checks.

Time after TXA or no TXA	**Finger prick test**	**Blood test from needle in vein**	**Heart rate, Blood pressure, breathing rate**	**Blood loss**	**Collect any Information about any treatments you receive**	**Check for any medical problems you have**	**Check if you have any problems if you had the injection into your muscles**	**Check for any medical problems your baby may have**
15 minutes	x		x	x	x	x	x	x
30 minutes	x		x	x	x	x	x	x
2 hours	x		x	x	x	x	x	x
4 hours	x	x	x	x	x	x	x	x
8 hours	x	x	x	x	x	x	x	x
12 hours	x	x	x	x	x	x	x	x
24 hours	x	x	x	x	x	x	x	x
Every day to discharge or day 7			x			x	x	x

4. How long will I be in this study?

You will be in the study until you leave hospital, or for seven days after you had your baby, whichever is sooner. If after leaving hospital and within seven days of giving birth, you or your baby become ill, please let the doctor named on this form know.

5. Will I benefit from taking part in this study?

We do not know if taking part in this study will help you personally or not. What we learn from this study will help doctors care for women at risk of having a large bleed after giving birth in the future. We hope that giving TXA before the caesarean section to women at risk of bleeding a lot, may prevent large bleeds. We hope that if TXA works when it is given in the muscle or drunk in a solution, these may help other women in the future that are in a situation where receiving an injection into a vein is not possible.

6. Could I be harmed by taking part?

Tranexamic acid is not a new drug and it is often used to treat people with other types of bleeding, such as when having an operation or after childbirth. Several studies suggest that it doesn't have any serious side effects. Sometimes it can cause nausea, vomiting, and diarrhoea. If you receive the injection in your muscles there is a small risk of redness, pain, and bruising at the injection sites in your muscles and there is a very rare risk of infection.

Previous studies that administered tranexamic acid to pregnant women did not identify harmful effects for the baby. A very small amount of tranexamic acid can pass into breast milk. Other studies have not found any harmful effects in babies who were breastfed by mothers who were given tranexamic acid. Your doctor will watch you and your baby, and give you the best available care if there are any problems. They will also tell the people running the study if you have any problems.

7. Can I change my mind about taking part?

Yes. You can stop taking part in the study, at any time. You just need to say something like, *"I've decided I don't want to be in this study anymore"*. Your doctor and the hospital staff will still care for you in the usual way. If you have any medical problems after you stop taking part, we ask that you still tell us about them.

8. What happens afterwards?

We will give you a card with the contact details of the study doctor at this hospital. Please keep this card safe. If after you leave hospital you or your baby become ill within seven days of having your baby, please contact the study doctor listed on the card. Also, please show this card to anyone who treats you for any illness.

If you would like to have a copy of the final results of this study, please let the doctor discussing this study with you know and s/he will make sure you receive a copy when the results are published.

9. What information do we keep private?

We will keep all information collected about you and your baby private and stored securely. The only people allowed to look at the information will be the staff who are running the trial at the London Coordinating Centre and a representative of the London School of Hygiene and Tropical Medicine (who sponsors the trial) in Zambia, as well as the regulatory authorities and Ethics Committees who

check that the study is being carried out correctly. The London Coordinating Centre may want to collect or copy some study information which will have your name on it such as the signed Consent Form. These will be destroyed or your personal details removed immediately after use.

We will publish the study results in medical journals so that other doctors and midwives can learn from them. We will not include your personal information in any study reports, so you will not be able to be identified. The study team may share data from the study with other researchers and the public, but your personal information will not be included.

10. What will happen to your blood samples?

Your finger prick blood samples will be prepared and then shipped securely via a specialised courier service to a Laboratory at the University Versailles Saint Quentin (France). They will measure the quantity of TXA in the samples. Our staff at the laboratory will not be able to identify you. All the blood samples taken from your vein will be tested at a local Laboratory in Zambia. Your samples will be destroyed safely after they have been analysed or latest at the end of the study.

11. Who is doing this study? Who can I contact about any questions, or if I have a problem?

The study is run by a team of researchers at the London School of Hygiene & Tropical Medicine (University of London) in the United Kingdom.

If you have any questions or concerns about the study, you should ask to speak with the study team who will do their best to answer your questions. You can contact the doctor in charge of the trial at this hospital at:

Name:	
Address:	
Telephone:	
Email:	

If you wish to complain formally, you can do this through the hospital's complaints procedure. Please ask the study doctors or midwives for details.

12. Who has reviewed the study?

To look after your interests, this study has been carefully checked by an independent group of people called a Research Ethics Committee. They agreed that it is okay for us to do this study. This study has been reviewed and has been given a favourable ethical opinion by a Research Ethics Committee called:

Research Committee address:	
Chairperson:	
Tel:	
Email:	

13. What if there is a problem?

If something goes wrong during the study, the London School of Hygiene & Tropical Medicine would be responsible for claims for any non-negligent harm.

14. What else do I need to know?

If you/the patient are injured as a result of being in this study, you should contact the study doctor. In the event of a bodily injury or illness directly resulting from the study product, the sponsor will pay for reasonable and necessary treatment. The sponsor is not responsible for medical expenses due to pre-existing medical conditions, any underlying diseases, any ongoing treatment process, your negligence or wilful misconduct, the negligence or wilful misconduct of the study doctor or the study site or any third parties. You do not lose any of your legal rights to seek compensation by signing this form.

- The study is organised by London School of Hygiene and Tropical Medicine (LSHTM, University of London, UK) and funded by the Wellcome Trust (UK) and the Bill and Melinda Gates Foundation (USA). None of these institutions are the makers of tranexamic acid.
- If you agree to take part, you will sign a separate consent form. We will give you a copy of your consent form and this information sheet.
- The study treatment is free. It will not cost you any money to take part in this study.
- If you return to hospital for any medical problem associated with the study, we will pay your travel costs.

HOSPITAL DETAILS

CONSENT FORM

WOMAN-PHARMACO TXA TRIAL

TITLE OF RESEARCH	A randomised controlled trial to assess the pharmacokinetics and pharmacodynamics of intramuscular, intravenous and oral administration of tranexamic acid in women giving birth by caesarean section.		
VERSION NUMBER	1.2 Zambia	**VERSION DATE**	28 AUGUST 2020
SITE ID NUMBER		**NAME OF RESEARCHER**	
PARTICIPANT SCREENING ID NUMBER			

STATEMENT OF PERSON GIVING CONSENT:

1. I confirm that I have read/have had read to me the information sheet for the above study and it was in a language I understand.
2. I have discussed with the doctor to my satisfaction and I have had the opportunity to ask questions.
3. I understand that my participation is voluntary. I have been given enough information about the research study to judge that I want to take part in it.
4. I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.
5. I understand that I will be given a copy of this consent form and the additional information sheet to keep for myself.
6. I understand that sections of my medical notes and those of my baby/ies may be looked at by responsible individuals involved in the study, monitors, auditors and representatives of the Ethics Committee and regulatory authorities to verify the procedures and/or data of the clinical trial. I give permission for these individuals to have direct access to these records.
7. I understand that my data (with all personal information removed) will be made freely available for the public.
8. I understand that the blood samples collected from me will be sent abroad, to France, for analysis and not stored for future research. The samples will not be labelled with any personal information, only a study identification number will be used.
9. I give permission for a copy of this consent form, which contains my personal information, to be made available to the Trial Coordinating Centre in London for monitoring purposes only.
10. I agree to take part in the above study, the WOMAN-Pharmaco TXA trial.

_____	_____	_____
Name of woman	Date	Signature / Thumbprint or other mark (if unable to sign)
_____	_____	_____
Name of witness	Date	Signature

(A witness not associated with the trial is needed if a patient cannot read or write)

STATEMENT OF PERSON OBTAINING INFORMED CONSENT:

I have fully explained this research to this participant and have given sufficient information, including about risks and benefits, to make an informed decision.

_____	_____	_____
Name	Date	Signature