INFORMATION FOR PATIENTS

INTERNATIONAL STUDY OF BLEEDING AFTER INJURY

Principal Investigator: Dr [name]
[Department]
[Hospital]

Sponsor: International Study of Bleeding After Injury,
London School of Hygiene & Tropical Medicine,
Keppel Street, London WC1E 7HT

World Health Organization

You are being invited to participate in a research study conducted by Dr. [name] because you acquired serious injury and have significant bleeding which require medical treatment.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family, or your family physician.

This study has been approved by the [Hospital name] Research Ethics Board and will be conducted in accordance with the applicable regulatory requirements and adherence to the guidelines of the International Conference on Harmonisation (ICH) and the requirements in the Declaration of Helsinki.

[Hospital] and the investigator Dr. [name] are under contract with the sponsor of this study and are receiving compensation to cover the costs of conducting the study. Your doctor will not receive a fee for enrolling you in the study.

In this hospital, patients with severe bleeding are given the usual emergency treatment for bleeding. The aim of this research study is to find a better treatment. We hope that the study treatment (tranexamic acid) will help clotting and so lessen the amount of blood lost and reduce the need for a blood transfusion. But the study treatment may cause clots where they are not needed. We hope to find that the treatment will do a little more good than harm but we don't yet know this. Please read the information below carefully and ask the doctor looking after you any questions you have.

1) Why is this research being done?

Severe bleeding is a common cause of death after injury and it is important to find better ways of reducing the amount of blood lost.

2) What is the purpose of this study?

Tranexamic acid is often used to reduce bleeding after major surgery such as heart operations. This study is being done to see if it can also reduce bleeding after major injury. Tranexamic acid is not a new drug and is an approved treatment for many common conditions that involve bleeding.

3) Who is doing the study?

Dr [name] is in charge of this study at this hospital. The study is co-ordinated by doctors at The University of London, UK.

4) A patient cannot be in this study if:

- He/she is known to be under 16
- He/she was injured more than 8 hours before arriving in hospital
- The doctor thinks there is a particular reason why tranexamic acid definitely **should not** be given
- The doctor thinks there is a particular reason why tranexamic acid definitely **should** be given

5) What has happened to you after you were included in this study?

You were given all the usual emergency treatments for bleeding, including fluids to replace the blood that you lost. You were also given a dose of either the active tranexamic acid or placebo (dummy treatment containing no active compound). The investigational or placebo medication will be injected intravenously (through the vein) as a slow injection over approximately 10 min. first as a loading dose and then as a maintenance dose over a period of eight hours. The choice of what to give (active treatment or placebo treatment) was made randomly by a computer at the University of Oxford, UK. The doctors looking after you do not know whether you got the active or the placebo. This information is kept on a confidential list in another hospital. The study involves no extra tests but your doctor will send brief details about how you have been to the Co-ordinating Centre in London. This information will be used in strict confidence by the people working on the study and will not be released under any circumstance.

Your participation in this study is expected to last until your discharge from the hospital or up to four weeks post randomisation.

6) What are the possible risks of being in the study?

Tranexamic acid is widely used and at the moment there is no conclusive evidence of serious side effects with short-term use. Tranexamic acid is NOT a new drug. Gastrointestinal disturbances (nausea, vomiting, diarrhea) may occur but disappear when the dosage is reduced. Giddiness and hypotension have been reported occasionally. Hypotension has been observed when IV injection is too rapid. To avoid this we are administering the bolus dose as an infusion over 10 min. In the event that you suffer injury as a result of participating in this research, no compensation will be provided for you by the [Hospital] or the investigator.

7) What are the possible benefits of being in the study?

We hope that tranexamic acid may help reduce blood loss. The knowledge that we gain from this study will help people with similar injuries in the future.

8) If you have any questions or problems, who can you call?

If you have any questions you can contact Dr. [name], [tel]

9) What information do we keep private?

All information about you and your injury will be kept private. The only people allowed to look at the information will be the doctors who are running the study, the staff at the Co-ordinating Centre and the regulatory authorities who check that the study is being carried out correctly. We will publish the results of the study in a medical journal so that other doctors can benefit from the knowledge, but your personal information will not be included and there will be no way that you can be identified. However, it is important to note that this original signed consent form and the data that follows, may be included in your health record.

10) Can the study end early for the participant?

The study treatment was given in the emergency situation. We hope that you will let us use information about how you got on, but if you do not want us to use it then please tell your doctor.

Your participation is voluntary and you may withdraw at any time and this will in no way affect the quality of care you receive at this institution. If you choose not to participate or end your participation, you will be treated with current standard therapy.

You have the option of removing your data from the study.

It is important for you to know that you can choose not to take part in the study. An alternative to the procedures described above is not to participate in the study and continue on just as you do now. Your study doctor will discuss this alternative with you.

11) What else do you need to know?

- The study is funded by the University of London and the World Health Organization, not the makers of tranexamic acid.
- The London School of Hygiene & Tropical Medicine (University of London) as the Co-ordinating Centre for the study accepts responsibility attached to its sponsorship of the study and, as such, would be responsible for claims for any non-negligent harm suffered by anyone as a result of participating in this study.
- In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities.
- Your continued participation should be as informed as your initial consent, so you should feel free to ask the clarification or new information throughout your participation.
- We will ask you to sign a separate consent form and give you a copy to keep.

If you have any questions regarding your rights as a research participant, you may contact: [name and telephone number of appropriate department in hospital]

PATIENT CONSENT FORM

INTERNATIONAL STUDY OF BLEEDING AFTER INJURY

PLEASE INITIAL BOX

1. I confirm that I have read and understood the information sheet Version 4, dated 23 August 2005, for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from The London School of Hygiene & Tropical Medicine or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study / for my information to be used in this trial. ☐
5. I understand that I can withdraw my consent at any time and my medical care will not be affected in anyway by my withdrawal. ☐
6. I understand that I will receive a signed copy of this form. ☐

Name of Patient	Date	Signature
Name of Person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature