INTERNATIONAL STUDY OF BLEEDING AFTER INJURY

Information and consent form for patients, relatives and representatives

If you have any questions about your participation in the International Study of Bleeding After Injury, please contact:

(INSERT HOSPITAL CONTACT DETAILS)

STUDY CO-ORDINATING CENTRE:
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This hospital is taking part in a research study to find ways to reduce severe bleeding after serious injury.

(1) You have been included in this study
(2) We would like to include you in this study

(3) We would like to include _____ (name of patient) in this study .
(Please circle the applicable option)

WHAT YOU SHOULD KNOW ABOUT RESEARCH STUDIES:

This form gives information about the study including the aims, risks and benefits of taking part.

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 _____ is in charge of this study at this hospital. The study is co-ordinated by doctors at The University of London.

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/will happen during this study?

You/the patient were/will be given all the usual emergency treatments for bleeding, including fluids to replace the blood that you lost. You/the patient were/will be also given a dose of either the active tranexamic acid or an inactive dummy medicine called saline. The dose was/will be given over a period of eight hours.

The choice of what to give (active treatment or dummy treatment) was made randomly by a computer in Oxford, UK. The doctors looking after you/the patient do not know whether you got the active or the dummy medicine. 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/the patient 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.

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.

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 _____

by telephoning _____

9) What information do we keep private?

All information about you/the patient and your/their 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.

10) Can the study end early for the patient?

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

11) What else do you need to know?

- The study is funded by the University of London and the World Health Organisation, not the makers of tranexamic acid.
- The London School of Hygiene & Tropical Medicine 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.

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CONSENT

(if needed)

I understand what the study is about and I am happy

1) to participate
2) for the details about my recovery to be used by the study

OR, if you are not the patient

3) for the below named patient to participate
4) for the details about the patient's recovery to be used by the study

Signature: _____

Date: _____

Name of the patient:_____

Name of the doctor requesting consent:

_____

Name of the person giving consent:

_____

If you are not the patient, what is your relationship?

_____