PI & Hospital name
Address
Tel, Email

INFORMATION FOR RELATIVES AND REPRESENTATIVES

INTERNATIONAL STUDY OF BLEEDING AFTER INJURY AND INTRACRANIAL BLEEDING SUBSTUDY

This hospital is taking part in a research study to find ways to reduce severe bleeding after serious injury. We would like to include (name of patient) in this study.

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 and injury to the head are given the usual emergency treatment. 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 and bleeding into the brain. 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 responsible doctor for 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.

4) A patient cannot be in this study if:

- he/she is known not to be legally adult
- 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
- she is pregnant
- the brain scan is normal

5) What will happen to the patient after he/she is included in this study?
The patient will be given all the usual emergency treatments for bleeding, including fluids to replace the blood that he/she lost. The patient will also be given a dose of either the active tranexamic acid or an inactive dummy medicine called saline. The dose will be given over a period of eight hours. The choice of what to give (active treatment or dummy treatment) will be made randomly by a computer at the University of Oxford, UK. The doctors looking after (patient name) will not know whether he/she gets the active or the dummy medicine. This information is kept on a confidential list in another hospital. It is routine practice to do a CT scan after a traumatic brain injury; this study involves doing a second CT scan within 24-48 hours of the injury. Doctor (doctor's name) will send brief details about how the patient is doing 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. A patient would normally be exposed to at least one CT scan; during this study an extra CT scan (within 24-48 hours) would be done. Level of exposure to X-ray radiation is about the same as (patient name) would receive naturally from the environment over eight months.

7) What are the possible benefits of being in the study?
We hope that tranexamic acid may help reduce blood loss and bleeding into the brain. 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) by telephoning (tel)

9) What information do we keep private?
All information about (patient name) and his/her 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 (patient name)'s personal information will not be included and there will be no way that he/she can be identified.

10) Can the study end early for the participant?
We hope that you will let us use information about how the patient got on, but if you do not want us to use it then please tell the doctor who is looking after the patient.

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 (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.
- We will ask you to sign a separate consent form and give you a copy to keep.

STUDY CO-ORDINATING CENTRE:
International Study of Bleeding After Injury, Room 180
London School of Hygiene & Tropical Medicine, Keppel Street, London WC1E 7HT
Tel +44 20 7299 4684
WWW.CRASH2.LSHTM.AC.UK

PI & Hospital name
Address
Tel, Email

Hospital Name:	
Patient Hospital ID:	
Randomisation Number:	
Name of Principal Investigator:	

RELATIVE AND REPRESENTATIVE CONSENT FORM

INTERNATIONAL STUDY OF BLEEDING AFTER INJURY and Intracranial Injury Substudy

PLEASE INITIAL BOX

1. I confirm that I have read and understood the information sheet Version 1, dated 6 June 2008, for the above study and have had the opportunity to ask questions. ☐
2. I understand that the patient participation is voluntary and that he/she is free to withdraw at any time, without giving any reason, without his/her medical care or legal rights being affected. ☐
3. I understand that sections of any of the patient's 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 his/her taking part in research. I give permission for these individuals to have access to the patient records. ☐
4. I agree for (patient name) to take part in the above study / for (patient name)'s information to be used in this trial. ☐
5. I understand that I can withdraw my consent at any time and the patient's medical care will not be affected in anyway by my withdrawal. ☐

_____	_____	_____
Name of relative or representative	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature