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INFORMATION SHEET FOR PARTICIPANTS AND THEIR REPRESENTATIVES

The CRASH-4 Trial

Short title: Clinical Randomisation of Antifibrinolytic in Symptomatic mild Head injury in older adults

Lay title: A trial of tranexamic acid in older adults after a head injury

INVITATION TO TAKE PART

We are inviting people aged 50 years or older who need to go to hospital because of a head injury to take part in our research study. This information sheet explains why the research is important, what it involves and the risks and benefits of taking part.

1. WHAT IS THE PURPOSE OF THE STUDY?

- Every year, over one million people in the United Kingdom suffer a head injury and need to go to hospital. Bleeding into the brain is a common and serious complication of head injury and older adults are at highest risk.
- Even a small bleed into the brain can cause disability and some patients can die if the bleeding is more severe.
- A drug called tranexamic acid is used to reduce the chance of people dying after bleeding into their brain from a head injury.
- However, we do not yet know if this drug can stop bleeding into the brain from happening in the first place.
- In this research study, we want to see if giving tranexamic acid soon after a head injury can prevent bleeding into the brain from starting in the first place and lead to better health outcomes.

2. WHO IS TAKING PART?

5,000 adults in England, Scotland and Wales, aged 50 years or older, with a head injury needing hospital care.

3. DO I HAVE TO TAKE PART?

Taking part is voluntary. You can discuss the study with the study team and ask any questions before deciding. If you do not want to take part, you can simply say 'I do not want to take part', this will not affect the care you receive.

4. CAN I CHANGE MY MIND ABOUT TAKING PART?

You can change your mind about taking part at any time.

5. WHAT DOES TAKING PART INVOLVE?

You will be given all the usual treatments for your head injury and any other medical condition you may have but in addition to this we will:

- Collect some extra information about your injury and any previous health problems.
- Give you 1 or 2 injections of tranexamic acid or a placebo (dummy treatment) into your thigh, shoulder or bottom, whichever is most appropriate for you. You will have an equal chance of getting either treatment. The treatments look identical so that neither you, your medical team nor the study team will know which treatment you receive.
- Collect information about your short term recovery and contact you if any information is missing up to one week after discharge from hospital.
- Collect your name, date of birth, postcode and NHS number (England and Wales) or CHI number (Scotland) , which will allow us to collect information about your recovery about one year later from your NHS medical records.

The study team will monitor you whilst in hospital for up to 28 days after your injury. If you are discharged within 28 days you will be given the study team's contact details on a card. If you are being treated for any illness, or if you return to hospital for any reason within 28 days after your injury, please present the card to your medical team.

6. WHAT ARE THE POSSIBLE RISKS?

Tranexamic acid is not a new drug and has been used for decades to reduce bleeding after operations and to treat other types of serious bleeding. Studies have shown that there are no serious side effects with short term use in head injury. There is a small risk of redness, pain, and bruising at the injection site. The study team will monitor you closely and will report any unexpected problems to the study organiser.

7. WHAT ARE THE POSSIBLE BENEFITS?

We hope that giving tranexamic acid will improve health outcomes for older adults after a head injury. The knowledge we gain from this study will improve the care of people with similar injuries in the future.

8. WILL MY INFORMATION BE KEPT PRIVATE?

The only people with access to your information are the study team looking after you, the researchers running the study from London School of Hygiene and Tropical Medicine (LSHTM) and the regulators who make sure the study is done properly. We will use your personal information to help us find your medical record in an NHS database (called NHS England or NHS Scotland or NHS Wales Informatics Service (NWIS)). This will allow us to check your recovery at one year without bothering you again. Your personal information will be kept in a safe place separate to the study information and will be deleted after use. Non-identifiable study information will be kept at LSHTM and will be shared with researchers worldwide for research, medical knowledge and patient care. More information about how we will keep your personal data safe is on the LSHTM website: https://www.lshtm.ac.uk/files/research-

participant-privacy-notice.pdf, the study website https://crash4.lshtm.ac.uk/ or at www.hra.nhs.uk/information-about-patients/. You can also find out more about how your information is used by asking one of the research team in person or by emailing crash4@lshtm.ac.uk or by calling 020 7299 4684 .

9. HOW WILL MY INFORMATION BE USED?

We will need to use your name, date of birth, NHS number (England and Wales) or CHI number (Scotland) and postcode for this study. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see it. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records. If you do not want this to happen, tell us and we will stop. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

10. WHO CAN I CONTACT WITH ANY QUESTIONS?

You can ask the study team or call NAME (study team lead) on XXXX-XXXX-XXX. You can also contact the Patient Advice and Liaison Service, known as PALS, with any questions, concerns or problems with this study, or if you would like to know the NHS complaint procedure. You can contact your nearest PALS team, PALS NAME, on XXXX-XXXX-XXX.

11. WHAT ELSE DO I NEED TO KNOW?

- The study treatment is free. Neither you nor the study team get paid for you taking part.
- The study is funded by J.P. Moulton Charitable Foundation and the National Institue of Health Research (NIHR) (not the treatment makers).
- LSHTM takes full responsibility for the study and will act as the Data Controller so is responsible for processing your information properly.
- LSHTM has insurance in place in the unlikely event that you are harmed as a direct result of taking part in the study. The NHS has insurance in place for clinical negligence and other negligent harm as a result of the clinical procedure being undertaken.
- Please let the study team know if you would like a copy of the trial results once it is available.