

LETTER EXPLAINING THE ROLE OF THE REPRESENTATIVE

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

Dear [representative's name],

Your friend or relative suffered a head injury needing hospital care. 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. We know that giving a drug called tranexamic acid to patients with bleeding into their brain from a head injury reduces their chance of dying. We are doing a study to see if this drug can prevent bleeding into the brain after head injury. We hope that this will lead to better health outcomes. We would like to include your friend or relative in this study.

Your friend or relative is unable to decide whether to take part in the study because of the mental confusion caused by their head injury. When a person cannot decide for themselves, someone with a personal relationship with them can make the decision for them. You have been chosen by the research team as a suitable person to make this decision. If you do not want to make this decision, just let the study team know and this will be respected.

You may be reading this:

- To decide whether your friend or relative should be included in the study or not; or
- If your friend or relative has already been included, to decide whether they should continue in the study or not.

The researcher will explain which applies to you.

Please consider what you know of your friend or relatives' wishes, feelings and interests. If you know they would not like to take part in research, please let the study team know. If you know of no reason they would object to taking part, please read the separate information sheet to help you decide. This information is what would have been given to your friend or relative if they were able to make the decision for themselves. It is written in future tense, as though they are deciding whether to take part.

If you agree for your friend or relative to be included, we will keep you fully informed during the study. You can let the study team know if you have any concerns or if you think your friend or relative should be withdrawn at any point. If they can make their own decisions later, they will be asked whether they would like to continue taking part.

If you have any questions, you are welcome to ask the study team at any time.

Please now read the information sheet and consent form.

Yours sincerely,