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**LEGAL REPRESENTATIVE INFORMATION SHEET – RELATIVE**

 (Final version 1.2:16/01/2024)

EU CTR Number: 2022-500587-35-01

Title of Study: **Tranexamic acid for hyperacute spontaneous IntraCerebral Haemorrhage (TICH-3)**

Name of Chief Investigator: Professor Nikola Sprigg

Local Researcher(s):

**Introduction**

As part of routine clinical care, research staff check if patients are eligible for research studies. Your relative or close friend, (we will use the term ‘relative’ in the remainder of the information sheet) was considered eligible to take part in the TICH-3 study. TICH-3 aims to assess whether the drug tranexamic acid reduces the risk of death and/or improves disability 6 months after stroke.

Either your relative gave permission themself, or if they were too unwell to decide for themself, either you or another legal representative advised us that in their opinion they would have agreed to take part.

**Why has my relative** **already had the study treatment?**

Because intracerebral haemorrhage is an emergency and the potential benefits of the study treatment (tranexamic acid) are likely to be related to how soon after stroke the treatment is given, every minute counts. We needed to decide about giving the treatment as quickly as possible so we will have asked your relative to give verbal permission (oral consent) to start with treatment. If they were not well enough to decide we will have asked you, or another relative if they were available to decide on their behalf. If no one was available a doctor will have given permission for them to go ahead with treatment. They are able to make this decision in accordance with emergency consent procedures.

For your relative to continue participating in the study, it is important for you to understand why this research is being done and what it involves. If, after taking consent from you on the patient’s behalf, the patient regains capacity we will take full consent from them regarding the trial. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask us if there is anything that is not clear to you, or if you would like more information. Take time to decide whether or not your relative would wish to continue to take part.

**What is the purpose of the study?**

When someone has a stroke caused by bleeding into the brain (intracerebral haemorrhage, ICH) permanent brain damage can occur and result in long term disability. There is also a chance that the bleeding can increase, which may cause worse disability or be life threatening. This happens in approximately 20-30% of patients with intracerebral haemorrhage. At present there is currently no available drug treatment that is effective at reducing the bleeding in the brain and improving the recovery after intracerebral haemorrhage. In this trial, we want to test whether it is possible to give a drug (tranexamic acid) to patients in the first few hours after intracerebral haemorrhage. We hope that we will be able to show that giving the drug tranexamic acid may reduce the risk of dying and being left with disability after stroke due to intracerebral haemorrhage.

Tranexamic acid is used as standard care in other emergency medical conditions due to bleeding, where it is has been proven to help stop bleeding.

In order to do a proper comparison, we need to give some participants the active drug and some people a dummy (placebo) treatment. In this trial the dummy treatment is salt water and half of the patients in the trial will receive an injection with the drug tranexamic acid and half will have an injection of salt water as a dummy (placebo) treatment.

The result from this study will help doctors decide whether tranexamic acid should be used routinely in patients with intracerebral haemorrhage to reduce risk of death and improve recovery.

# Why has my relative been invited?

Your relative has been chosen because they have had a stroke caused by bleeding into the brain – called an intracerebral haemorrhage - and the doctors treating them felt that they fit the requirements for this research project. At present they are not able to tell us whether or not to continue to take part, so we are asking your opinion of what you think they would want if they were able to decide themselves. If you do decide they would wish to continue to take part you will be given this information sheet to keep and be asked to sign a consent form. We are inviting approximately 5500 participants with intracerebral haemorrhage to take part from around the UK and worldwide.

# Do they have to take part?

It is up to you, at the time being, to decide whether or not they take part. If you do decide they would wish to take part, you will be given this information sheet to keep and be asked to sign a consent form. Your relative is still free to withdraw at any time and without giving a reason. This would not affect their legal rights.

# What will happen to my relative if they take part?

Your relative’s involvement in the study will last for 6 months.

In this study the treatment (either tranexamic acid or dummy) was given as an injection via a drip over approximately 8 hours as soon as possible after the onset of their stroke.

We selected which treatment was received randomly (like tossing a coin) because this is how most clinical trials are carried out as it is the best way to find out if a treatment works without bias. Using randomisation to put patients into treatment groups is the best way to get a true answer as to whether a treatment works or not. You (or their doctors) will not know if they received the drug or the dummy.

During the first 7 days after stroke members of the clinical and research team will monitor your relative’s condition and record relevant information from their medical notes. This will include the investigation and treatment they receive as part of standard clinical care. For example, blood pressure lowering medication, treatment on a stroke unit and results of any further brain scans.

We ask permission to contact you or your relative to complete a questionnaire via post or email to check on their condition 6 months after their stroke. The questionnaire will involve asking how they are able to move around, about how they feel life has been affected by the stroke and some brief memory tests. If they are unable to complete the questionnaire themselves, we will ask you (or another relative, close friend or carer who is with them at the time) to complete it on their behalf.

Other than described here, your relative’s treatment will be ***exactly the same*** as for all stroke patients with intracerebral haemorrhage.

# Expenses and payments

Participants will not be paid to participate in the study. There will be no additional travel as result of taking part in this study.

# What are the possible disadvantages and risks of taking part?

Tranexamic acid is a medicine which has been used for many years to treat bleeding problems. It is currently used in patients with nose bleeds, bleeding from the bladder or womb and heavy bleeding after surgical operations or after trauma. It increases blood clotting quickly and effectively for short periods in patients with a bleeding condition and that is why we are using it in this study. Treatment with any drugs can result in possible side effects and the side effects from tranexamic acid are generally mild. They can include diarrhoea, low blood pressure and dizziness. The drug can also sometimes affect colour vision but this is rare.

However, because the treatment works by stopping bleeding there is a chance it can cause an increase in blood clot formation. This can occur in the legs (deep vein thrombosis, DVT) or the lungs (Pulmonary embolism, PE) and is potentially very serious and maybe even life threatening. However, in previous studies in stroke patients, and in people with emergency bleeding due to trauma, involving thousands of patients, tranexamic acid was safe and did not increase blood clots.

Your relative will have undergone CT brain imaging as part of their standard clinical care to confirm the diagnosis of intracerebral haemorrhage and the clinical team may repeat this brain imaging to monitor progress. If your relative participates in this trial, the imaging will be shared with the study team so they can better understand the effects of the study medication. There is no additional brain imaging as part of this study and no additional radiation exposure if your relative participates in this study

# What are the possible benefits of taking part?

We cannot promise the study will benefit your relative but the information we get from this study may help reduce how badly the stroke affects your relative in short and long term by reducing bleeding in the brain. The information we get from this study will help in deciding the best treatments for stroke patients in the future due to intracerebral haemorrhage.

# What happens when the research study stops?

We would like to follow your relative’s progress over six months (questionnaire at 180 days). When all participants have been followed up, the trial results will be analysed and published in a medical journal. We will offer to send your relative a copy of the results.

# What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers’ contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting [please provide the contact details of patient complaint department for the hospital].

In the event that something does go wrong and your relative is harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your relative’s legal costs. The normal standard local Irish complaints mechanisms will still be available to you.

# Will my relative’s taking part in the study be kept confidential?

Participants’ confidentiality will be safeguarded during and after the study. We will follow ethical and legal practice and all information about participants will be handled in confidence. We will comply with Article 35 of the EU Regulation 536/2014.

If your relative joins the study, we will use information collected from them [and their medical records] during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws as well as EU GDPR laws, the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your relative’s information and using it properly. Your relative’s rights to access, change or move their information are limited as we need to manage your relative’s information in specific ways to comply with certain laws and for the research to be reliable and accurate.

To safeguard your relatives rights, we will use pseudonymised data until the end of the trial. ‘Pseudonymised data’ is information that has been altered to protect privacy by removing direct identifiers (such as your name, address, date of birth), but the research staff will still be able to identify you through your personal information if required

You can find out more about how we use participants information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to your relative as a research participant and we will do our best to meet this duty.

Your relatives personal data (address, telephone number, family doctor details, relative (next of kin) details) will be securely kept in your local Irish Hospital and at the Tallaght University Hospital, it will not be shared with the University of Nottingham in the UK. It will be kept for 12 months after the end of the study in case we need to contact them, for example for safety reasons or with study results.Your relative’s personal data (address, telephone number) will be kept for 12 months after the end of the study in case we need to contact them, for example for safety reasons or with study results. After this, your relative’s personal data (address, telephone number) will be anonymised however we will securely retain copies of your relative’s consent form. Your relative will not be identifiable in any of the data published in the study.. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the Irish research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our irrevocably anonymised research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is anonymised (so that your relative could not be identified).

# What will happen if I don’t want my relative to carry on with the study?

Your relative’s participation is voluntary and they (or you acting on their presumed wishes) are free to withdraw at any time, without giving any reason, and without their legal rights being affected. If you withdraw, we will no longer contact you or collect any information about them from you. Your relative’s personal data will be securely discarded after they have withdrawn. To protect the integrity of the study we will keep the pseudonymised information about them that we have already obtained. The pseudonymised data may have already been used in some analyses and may still be used in the final study analyses. We will always use the minimum information possible.

If your relative or you decide to withdraw from the trial, you may choose to give permission for the research team to contact the family doctor for some final information about your status. This would only be done with your permission, and we would record that permission, and collect the minimum amount of data possible for final study analysis.

# What will happen to any samples they give?

We will not be collecting samples as part of this trial.

# Will any genetic tests be done?

No.

# What will happen to the results of the research study?

The results of the study will be published in medical journals. However, any personal details will be kept strictly confidential and no information will be given through which your relative can be identified. At the end of the trial the research team will send a summary of the results either via post or email.

# Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by NIHR HTA Programme Project grant NIHR129917.

# Who has reviewed the study?

All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your relative’s interests. This study has been reviewed and given favourable opinion by the National Research Ethics Committee in Ireland (NREC) as well as the Health Products Regulatory Authority (HPRA) overseen by the European Medicine Agency.

Further information and contact details

Trials Office

Nottingham Stroke Trials Unit

D floor South block, Room 2123

Queens Medical Centre

University of Nottingham

NG7 2UH

**Tel:** +44115 823 1782

**Email:** MS-TICH-3-inter@nottingham.ac.uk

**Thank you for reading this information sheet**