

**PARTICIPANT INFORMATION SHEET** (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)**

**This form pertains to consent to continue in the *study***

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. You were eligible to take part in the TICH-3 study. TICH-3 aims to assess whether a drug called tranexamic acid reduces the risk of death and/or improves disability 6 months after having a stroke.

Either you gave permission to participate or if you were too unwell to decide for yourself, a legal representative advised us that in their opinion you would have agreed to take part.

**Why have I already been consented and 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 you to give verbal permission (oral consent) to start with treatment. If you were not well enough to decide we will have asked a relative or other legal representative on your behalf if they were available. If no one was available a doctor will have given permission for you to go ahead with treatment. They are able to make this decision in accordance with emergency consent procedures.

To continue participating in the study, it is important for you to understand why this research is being done and what it involves. 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 you 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 treatment in other emergency medical conditions due to bleeding, where it has been proven to help stop bleeding.

In order to make 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. Regardless of what intervention you receive, you will still receive all the necessary standard care.

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 have I been invited?

You have been chosen because you have had a stroke caused by bleeding into the brain – called an intracerebral haemorrhage and the doctors treating you felt that you fit the requirements to participate in this research project. It is up to you to decide whether or not to continue to take part. If you do decide 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 world.

# Do I have to take part?

It is your choice to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

# What will happen to me if I take part?

Your 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 your stroke.

We selected which treatment you 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 your doctors) will not know if you received the drug or the dummy.

During the first 7 days after your stroke members of the clinical and research team will monitor your condition and record relevant information from your medical notes. This will include the investigation and treatment you 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 your permission to contact you with a questionnaire to complete via post or email, to check your condition 6 months after your stroke. The questionnaire will involve asking how you are able to move around, about how you feel your life has been affected by the stroke and some brief memory tests. If you are unable to complete the questionnaire yourself we will ask a relative, friend or carer to complete it on your behalf.

Other than described here, your treatment will be ***exactly the same*** as for all stroke patients with intracerebral haemorrhage to save life and aid recovery.

# 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.

You will have undergone CT brain imaging as part of your standard clinical care, and the clinical team may repeat this brain imaging to monitor your progress. If you participate in this trial, your brain 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 you participate in the study.

# What are the possible benefits of taking part?

We cannot promise the study will benefit you but the information we hope to obtain from this study may help reduce how badly your current stroke affects you in the short and long term by reducing bleeding in the brain. The information we obtain 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 progress over six months (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 a copy of the results to all participants.

# 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 you are 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 legal costs. The standard local Irish complaints mechanisms will still be available to you.

# Will my 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 EU Regulation 536/2014.

If you join the study, we will use information collected from you [and your 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 while also abiding by 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 information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate.

To safeguard your rights, we will use pseudonymised data until the end of the trial. Pseudo-anonymised 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 your 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 you as a research participant and we will do our best to meet this duty.

Your 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. Your personal data (address, telephone number) will be kept for 12 months after the end of the study in case we need to contact you, for example for safety reasons or with study results. After this, your personal data (address, telephone number) will be anonymised however we will securely retain copies of your consent form. You 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 or consent forms.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share your 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 irrevocably anonymised (so that you could not be identified).

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

Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw from the study, we will no longer contact you or collect any further information about you or from you. Your personal data will be securely discarded after you have withdrawn. To protect the integrity of the study we will keep the pseudonymised information about you that we have already obtained, and your written consent form. 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.

You may decide you do not wish to carry on with the study but may choose to give permission for the research team to collect some final information about your status from a family member or a family doctor. 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. If you were to lose capacity during the trial and were unable to decide whether you would like to continue in the trial, and an objection to your continuation was raised by your legal representative (relative, or other legal representative); then you would be withdrawn from the study. If you were to be withdrawn, we will no longer collect any information about you or from you, but we will keep the information about you that we have already obtained. As above this information 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.

# What will happen to any samples I 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 you 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 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

TICH-3 Trials Office

Nottingham Stroke Trials Unit

D floor South block, Room 2123

Queens Medical Centre

University of Nottingham

NG7 2UH

**Tel:**  +44 115 823 1782

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

**Thank you for reading this information sheet**