A drawing of a brain

Description automatically generated with medium confidence**Graphical user interface, application

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**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**

You have been asked to act as a professional legal representative to consider if you think that the patient you have been asked about (referred to as the potential participant in this document) should 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 due to intracerebral haemorrhage (ICH).

We ask for your professional opinion as a legal representative as the potential participant is too unwell to decide for themselves, and no relatives are immediately available to ask their opinion.

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 need to decide about giving the treatment as quickly as possible so ideally we ask the patient to give verbal permission (oral consent) to start with treatment. As they are not well enough to decide, and no relatives are immediately available you have been asked to decide on their behalf. You are able to make this decision in accordance with emergency consent procedures.

For participants who are enrolled - following agreement by a professional legal representative - as soon as relatives are available or when the patient regains capacity, a detailed information sheet will be provided, and written consent sought for continuation in the trial.

More detailed information about the TICH-3 study is presented below.

**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 is has been proven to stop bleeding.

In order to do a proper comparison, this is a randomised placebo-controlled trial. In this trial, half of the patients will receive an injection with the drug tranexamic acid and half will have an injection of salt water (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 potential participant been invited?

The potential participant has been chosen because they have had a stroke caused by intracerebral haemorrhage - and the doctors treating them feel that they fit the requirements for this research project. At present they are not able to tell us whether they would 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 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 take part, you will be given this information sheet to keep and be asked to sign a consent form. The potential participant is still free to withdraw at any time and without giving a reason. This would not affect their legal rights. 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.

# What will happen to potential participant if they take part?

The potential participants involvement in the study will last for 6 months.

In this study the treatment (either tranexamic acid or saline) is administered as intravenous infusion through a venous cannula with a loading dose infusion over 10 minutes followed by an infusion over 8 hours.

During the next 7 days members of the clinical and research team will monitor the potential participants 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 the potential participant to complete a questionnaire via post or telephone 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 a relative, friend or carer who is with them at the time to complete it on their behalf.

Other than described here, the potential participants treatment will be ***exactly the same*** as for all stroke patients with intracerebral haemorrhage.

# 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 emergency patients with bleeding after trauma, labour or surgery. 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 at the dose used in this study (2g tranexamic acid) was safe and did not increase blood clots.

The potential participant 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 potential participants but the information we get from this study may help reduce how badly the stroke affects your potential participants 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 potential participant’s 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 the potential participants 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 the potential participants 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 legal representative’s legal costs. The standard local Irish complaints mechanisms will still be available to you.

# Will the participant taking part in the study data 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.

After your initial assent for administration of IMP we will get full consent from either the patient or their relative to access their personal information, medical records and follow them up for the next 180 days.

The details on data processing is for information only and you are not being asked to provide permission/assent/consent to process the patient’s data for this study.

If the potential participants join 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 the potential participants information and using it properly.

To safeguard the participant’s 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 the participant’s name, address, date of birth), but the research staff will still be able to identify the participant through their 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 the potential participant, and we will do our best to meet this duty.

The participant’s personal data (address, telephone number, family doctor details, relative (next of kin) details) will be securely kept in their local Irish Hospital and at the Tallaght University Hospital, it will not be shared with the University of Nottingham in the UK. The participant’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, the participant’s personal data (address, telephone number) will be anonymised however we will securely retain copies of the participant’s consent form. They 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 the participants confidentiality, only members of the research team given permission by the data custodian will have access to the participant’s personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our 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 the potential participants to carry on with the study?

The 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 they withdraw, we will no longer collect any information about them or from you. However to protect the integrity of the study ~~but~~ we will keep the pseudonymised information about the participant that we have already obtained; this pseudonymised information may have already been used in some analyses and may still be used in the final study analyses. W~~e~~ will always use the minimum information possible.

You may decide that 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 the participant’s status from another 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.

# 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 participants could 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 the participants 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.

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**Thank you for reading this information sheet**