ISRCTN97695350 https://doi.org/10.1186/ISRCTN97695350

Tranexamic acid for very early bleeds in the brain

Submission date
11/05/2021

Recruitment status
Recruiting

Registration date
21/06/2021

Overall study status
Ongoing

Last Edited
28/08/2024

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Tranexamic acid is a standard treatment in bleeding emergencies such as trauma and childbirth, where it reduces deaths from bleeding. A recent study showed that tranexamic acid given within 8 hours of a bleed on the brain is safe and prevents hematoma (abnormal collection of blood) growth. There was also a small reduction in the number of patients who died within the first 7 days. The study was not large enough to show whether there were effects on long-term disability. Tranexamic acid is cheap (£12) and easy to administer. If it is effective it could make a difference to patients with a bleed on the brain and their families worldwide.
The researchers have worked closely with stroke survivors and their carers to design this study. They told them that increased survival is important, but most people would not want to be alive at the expense of very severe disability, and also that 3 months is too early to measure recovery after stroke 6 months is more appropriate. The researchers discussed emergency consent in detail, and their advisors suggested that most people would be happy with the emergency consent procedure for this study. They also would prefer a blinded study where participants do not know which treatment they receive.

Who can participate?
Patients most likely to benefit from the treatment - those within 4.5 hours of the start of stroke symptoms

What does the study involve?
Patients will be approached about the study in the emergency department as soon as the brain scan confirms bleeding in the brain. The patient will be asked if they want to take part in the study; if they agree, a computer will decide, akin to the toss of a coin, whether they get an injection of tranexamic acid into a vein, or whether they receive saltwater as a placebo. The researchers will use a rapid emergency consent process, in accordance with ethical guidelines. It will be decided by chance which treatment the participants receive and it will not be possible for the doctor or the patient to know if they receive the tranexamic acid or placebo as the treatment packs look identical. It will be one injection, and then normal standard care will be given. The researchers will also contact people at 6 months after their stroke to assess their recovery and quality of life.

What are the possible benefits and risks of participating?
Tranexamic acid may stop participants from having a further bleed and may help them recover from the stroke but this is not guaranteed. The results of the study will help the treatment of stroke patients in the future. A risk of seizures has been demonstrated with tranexamic acid use in cardiac surgery where high doses of TXA are used. The proposed dose for this study is well below the dose associated with increased seizure risk. A recent traumatic brain injury study demonstrated a reduced death rate in patients given tranexamic acid. A recent study also revealed no increased risk of thromboembolic events (blood clots).

Where is the study run from?
University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
May 2021 to February 2028

Who is funding the study?
National Institute for Health Research (NIHR) (UK) and Programme Hospitalier de Recherche Clinique (PHRC) (France)

Who is the main contact?
Dr Tiffany Hamilton
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Study website
http://tich-3.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2021-001050-62

IRAS number
297457

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 297457, HTA - NIHR129917

Study information

Scientific Title
Tranexamic acid for hyperacute primary intracerebral haemorrhage (TICH-3)

Acronym
TICH-3

Study objectives
Does tranexamic acid (TXA) improve outcomes when given within 4.5 hours after intracerebral haemorrhage (ICH)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/11/2021, East Midlands - Nottingham 2 REC (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8169; Nottingham2.rec.nra.nhs.uk), ref: 21/EM/0243

Study design
Pragmatic phase III prospective blinded randomized placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Hyperacute primary intracerebral haemorrhage (stroke)

Interventions
Pragmatic phase III prospective blinded randomised placebo-controlled trial performed in two phases: a 30-month internal pilot phase with pre-specified progression criteria then the main phase. Using a pragmatic design with emergency consent processes, simple randomisation and minimal data collection will optimise enrolment and the blinded design will minimise bias.

Participants are randomised to receive intravenous TXA 2 g given as 1 g bolus in 100 ml normal saline 0.9% infusion over 10 min and 1 g infusion in 250 ml normal saline 0.9% over 8 hours or a placebo (normal saline 0.9%) administered by an identical regimen. Randomisation will be to TXA vs placebo in a 1:1 ratio.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Tranexamic acid

Primary outcome measure
Death at 7 days, measured by the number of participants who have died by Day 7

Secondary outcome measures
1. Disability measured by modified Rankin Scale (mRS) at Day 180
2. Venous thromboembolism/ischaemic events/seizures measured by review of medical notes at Day 7
3. Quality of life measured by EQ-5D visual analogue score (VAS) at Day 180
4. Cognition measured by AD-8 at Day 180

5. Health economics (use of antihypertensive medication, Do Not Resuscitate orders, admission to intensive care, neurosurgical intervention, hospital length of stay and discharge disposition) measured by review of medical notes at Day 180

Overall study start date
01/05/2021

Completion date
01/02/2028

Eligibility

Key inclusion criteria
Adult patients with ICH confirmed on brain imaging within 4.5 hours of symptom onset

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
5500

Key exclusion criteria
Current participant exclusion criteria as of 01/03/2023:
1. Patient with a known indication for TXA treatment (e.g. traumatic brain injury)
2. Patient with contraindication for TXA treatment
3. Patient known to be taking therapeutic anticoagulation with warfarin or low molecular weight heparin at the time of enrolment. Patients taking direct oral anticoagulants can be included and are not excluded.
4. Massive ICH for which haemostatic treatment seems futile (This would ordinarily be when haematoma volume is estimated as larger than 60ml)
5. Severe coma (Glasgow Coma Scale <5)
6. Decision was already taken for palliative (end of life) care with the withdrawal of active treatment

Previous participant exclusion criteria:
1. Indication for TXA
2. Patient known to be taking anti-coagulation
3. Glasgow Coma Scale (GCS) <5
4. Estimated haematoma volume (HV) >60 ml
5. Palliative care

Date of first enrolment
23/03/2022

Date of final enrolment
01/08/2027

Locations

Countries of recruitment
Denmark

England

France

Georgia

Ireland

Italy

Malaysia

Northern Ireland

Scotland

Spain

Sweden

Switzerland

United Kingdom

Wales

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Sponsor type
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https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Programme Hospitalier de Recherche Clinique

Results and Publications

Publication and dissemination plan
Protocol paper to be published at a later date. Simultaneous oral presentation at a large international stroke conference and publication in high impact journal. Stroke survivors and carers will inform dissemination to patients and public which is likely to include social media and a roadshow.

Intention to publish date
01/07/2028

Individual participant data (IPD) sharing plan
An anonymised dataset, collected during the duration of the trial by the University of Nottingham, will be stored securely and in a password-protected database by the University of

Nottingham. Individual anonymised participant data will be shared with the Virtual International Stroke Trials Archive (VISTA).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	07/10/2022	16/05/2023	No	No
Protocol file	Protocol for the CTIS EU countries version 4.2	30/03/2023	16/05/2023	No	No
HRA research summary			28/06/2023	No	No