# Tranexamic acid for very early bleeds in the brain

Submission date	<b>Recruitment status</b> Recruiting	[X] Prospectively registered		
11/05/2021		[X] Protocol		
Registration date 21/06/2021 Last Edited 05/11/2025	Overall study status Ongoing  Condition category Circulatory System	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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#### Contact information

#### Type(s)

Scientific

#### Contact name

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### Additional identifiers

#### Clinical Trials Information System (CTIS)

2021-001050-62

#### Integrated Research Application System (IRAS)

297457

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

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

#### Key secondary outcome(s))

- 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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

United Kingdom

England

Scotland

Wales

Denmark

France

Georgia



Malaysia

Spain

Sweden

**Switzerland** 

### Study participating centre Luton & Dunstable University Hospital

Lewsey Rd Luton United Kingdom LU4 0DZ

#### Study participating centre South West Acute Hospital

124 Irvinestown Road Enniskillen United Kingdom BT74 6DN

### Study participating centre Torbay Hospital

Newton Rd Torquay United Kingdom TQ2 7AA

### Study participating centre King's College Hospital

Denmark Hill Brixton London United Kingdom SE5 9RS

#### Study participating centre Morriston Hospital

Heol Maes Eglwys Morriston Swansea United Kingdom SA6 6NL

## Study participating centre Royal Derby Hospital

Derby United Kingdom DE22 3NE

#### Study participating centre Yeovil Hospital

Higher Kingston Yeovil United Kingdom BA21 4AT

#### Study participating centre Royal Victoria Hospital

274 Grosvenor Road Belfast United Kingdom BT12 6BA

#### Study participating centre Northwick Park Hospital

Watford Road Harrow United Kingdom HA1 3UJ

#### Study participating centre Peterborough City Hospital

Edith Cavell Campus Bretton Gate Bretton Peterborough United Kingdom PE3 9GZ

## Study participating centre Arrowe Park Hospital

Arrowe Park Road Upton Wirral United Kingdom CH49 5PE

## Study participating centre Salford Royal Hospital

Stott Lane Salford Manchester United Kingdom M6 8HD

### Study participating centre Southampton General Hospital

Tremona Road Southampton United Kingdom SO16 6YD

### Study participating centre The Royal Victoria Infirmary

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### Study participating centre St George's Hospital

Blackshaw Road London United Kingdom SW17 0QT

### Study participating centre Royal London Hospital

Whitechapel London United Kingdom E1 1BB

#### Study participating centre Royal Stoke University Hospital

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## Study participating centre Victoria Hospital

Hayfield Road Kirkcaldy United Kingdom KY2 5AH

#### Study participating centre Musgrove Park Hospital

Parkfield Drive Taunton United Kingdom TA1 5DA

#### Study participating centre Royal Devon and Exeter Hospital

Barrack Road Exeter United Kingdom EX2 5DW

#### Study participating centre Gloucestershire Royal Hospital

Great Western Road

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#### Study participating centre Royal infirmary of Edinburgh

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## Study participating centre Royal United Hospitals

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### Study participating centre West Suffolk Hospital

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#### Study participating centre Nottingham City Hospital

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#### Study participating centre Craigavon Area Hospital

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## Study participating centre Watford General Hospital

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## Study participating centre Southmead Hospital

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#### Study participating centre Royal Hallamshire Hospital

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## Study participating centre The James Cook University Hospital

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### Study participating centre Leighton Hospital

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### Study participating centre Royal Preston Hospital

Sharoe Green Lane North Fulwood Preston United Kingdom PR2 9HT

#### Study participating centre Northampton General Hospital

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## Study participating centre The Countess of Chester Hospital

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## Study participating centre Glasgow Royal Infirmary

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#### Study participating centre Sunderland Royal Hospital

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#### Study participating centre Princess Royal University Hospital

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## Study participating centre Bradford Royal Infirmary

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### Study participating centre Southend Hospital

Prittlewell Chase Westcliff-on-Sea United Kingdom SSO 0RY

#### Study participating centre University College London Hospital

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#### Study participating centre Aberdeen Royal Infirmary

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#### Study participating centre Kent and Canterbury Hospital

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### Study participating centre Charing Cross Hospital

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### Study participating centre Hospital Pengajar UPM

Persiaran Mardi - Upm Serdang Malaysia 43400

#### Study participating centre Hospital Queen Elizabeth

13a Jalan Penampan Kota Kinabalu Malaysia 88200

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Tsinandali Street 9 Tbilisi Georgia 0144

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#### Study participating centre Cork University Hospital

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#### Study participating centre The Mater Misericordiae University Hospital

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### Study participating centre St. James Hospital

James St

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#### Study participating centre St Vincents University Hospital

Elm Park Dublin Ireland D04 T6F4

## Study participating centre Tallaght University Hospital

The Meath Foundation Tallaght Dublin Ireland D24 NR04

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#### Study participating centre Leicester Royal Infirmary

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#### Study participating centre Queen Elizabeth Hospital

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#### Study participating centre Altnagelvin Area Hospital

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#### Study participating centre Northumbria Specialist Emergency Care Hospital

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#### Study participating centre Pinderfields Hospital Aberford Road

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#### Study participating centre Doncaster Royal Infirmary

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#### Study participating centre Eastbourne District General Hospital

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#### Study participating centre Royal Alexandra Hospital

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## Study participating centre Insel Gruppe AG (Bern)

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#### Study participating centre Uppsala University Hospital

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## Study participating centre Tallaght University Hospital

Stroke Unit Tallaght Dublin Ireland D24 NR0A

## Study participating centre Glan Clwd Hospital

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### Study participating centre

Klinik Hirslanden

Stroke Center Klinik Hirslanden Witellikerstrasse 40 Zürich Switzerland 8032

#### Study participating centre LTD Urgent Neurological Clinic Neurology

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#### Study participating centre ASST Ovest Milanese

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#### Study participating centre Presidio Ospedale San Carlo

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### Study participating centre Azienda USL Toscana Nord Ovest

U.O Neurologia Ospedale delle Apuane Azienda USL Toscana Nord Ovest Via Enrico Mattei, 21 Massa Italy 54100

#### Study participating centre Hôpital Jean Minjoz

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## Study participating centre CHU Dijon Bourgogne

Service de Neurologie CHU Dijon Bourgogne 14 Rue Paul Gaffarel Dijon France 21000

## Study participating centre CHU Lyon

Service de Neurologie Vasculaire CHU Lyon, Hôpital Neurologique 59 Boulevard Pinel Bron Lyon France 69500

#### Study participating centre Hôpital Nord Laennec

Unité Neurovasculaire Hôpital Nord Laennec, CHU Nantes 4ème étage aile ouest Boulevard Jacques-Monod, Cedex 1 Nantes France 44093

#### Study participating centre Centre Hospitalier Sud Francilien

Service de Neurologie du Pr Smadja Centre Hospitalier Sud Francilien 116 boulevard Jean Jaurès Corbeil Essonnes Paris France 91100

#### Study participating centre Hôpital Universitaire de la Pitié-Salpêtrière

Service des Urgences Cérébro-Vasculaires Hôpital Universitaire de la Pitié-Salpêtrière 184 Rue Faubourg Saint Antoine Paris France 75012

### Study participating centre Hôpital Lariboisière

Département de Neurologie Hôpital Lariboisière APHP 2 Rue Ambroise Paré Paris France 75010

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#### Study participating centre Hôpital Foch

Service de Neurologie et Unité Neurovasculaire Hôpital Foch 40 Rue Worth, Cedex Suresnes France 92151

### Study participating centre Hôpital André Mignot

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## Study participating centre CHU Poitiers

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## Study participating centre University Hospital of Wales

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Study participating centre University Hospital Hairmyres

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## Study participating centre Rigshospitalet

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### Sponsor information

#### Organisation

University of Nottingham

#### **ROR**

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**

#### 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**

Date Date Peer Patient-

Output type	Details	created	added	reviewed?	facing?
HRA research summary			28/06 /2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11 /2025	No	Yes
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
Study website	Study website	11/11/2025	11/11 /2025	No	Yes