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Tranexamic acid (and Desmopressin) 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
23/02/2026

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 (TICH-3), patients taking antiplatelets and within 24 hours of the start of stroke symptoms (DASH-2)

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?
TICH-3: May 2021 to February 2028

DASH-2: February 2026 to September 2027

Who is funding the study?
TICH-3: National Institute for Health Research (NIHR) (UK) and Programme Hospitalier de Recherche Clinique (PHRC) (France)

DASH-2: National Institute of Health Research for Patient Benefit (NIHR RfPB)

Who is the main contact?
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Contact information

Type(s)
Scientific

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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) and Desmopressin for reversal of Antiplatelet drugs in Stroke due to haemorrhage (DASH)-2

Acronym
TICH-3 / DASH-2

Study objectives
Current study objectives as of 23/02/2026:

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

For patients also taking antiplatelets, does desmopressin improve outcomes when given 24 hours after intracerebral haemorrhage (ICH)? Either independently or in combination with TXA.

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Previous 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)
1. 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
2. Approved 15/01/2026, East Midlands - Nottingham 2 REC (Health Research Authority, Redman Place, Stratford, London, E20 1 JQ, United Kingdom; 0207 104 8000; nottingham2.rec@hra.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
Current interventions as of 23/02/2026:

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.

Master Protocol (TICH-3) 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.

Optional sub-study (DASH-2) where participants are randomised to receive intravenous desmopressin given as 20 µg in 50 ml Sodium Chloride 0.9% over 20 minutes or a placebo (normal saline 0.9%) administered by an identical regimen. Randomisation will be to desmopressin vs placebo in a 1:1 ratio.

Previous 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, desmopressin

Primary outcome(s)
Current primary outcome(s) as of 23/02/2026:

TICH-3: Death at 7 days, measured by the number of participants who have died by Day 7

DASH-2: Death or dependency at Day 180

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Previous primary outcome(s):

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

Key secondary outcome(s))
Current key secondary outcome(s) as of 23/02/2026:

TICH-3:
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

DASH-2:
1. Safety: Symptomatic hyponatraemia or fluid overload at 24 hours (as defined in the protocol); early mortality < 7days, <28 days, and up to day 180; serious adverse events (including thrombotic events) up to day 180.
2. Functional/other: Quality of Life (EuroQol, EQ-5D-5L, VAS), and cognition (AD-8) at day 180.
3. Health economics: Health economic assessment (EQ-5D), length of hospital stay, discharge destination.

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Previous 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
Current key inclusion criteria as of 23/02/2026:

TICH-3: Adult patients with ICH confirmed on brain imaging within 4.5 hours of symptom onset

DASH-2: Adult patients taking antiplatelets with ICH confirmed on brain imaging within 24 hours of symptom onset

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Previous 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

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 23/02/2026:

TICH-3 comparison:
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

DASH-2 comparison:
1. Massive ICH for which haemostatic treatment seems futile (This would ordinarily be when haematoma volume is estimated as larger than 60ml (+/-10%))
2. Aneurysmal subarachnoid haemorrhage
3. Haemorrhage known to be due to transformation of infarction
4. Haemorrhage known to be due to a thrombolytic drug,
5. Haemorrhage known to be due to venous thrombosis,
6. Risk/s of fluid retention associated with desmopressin judged clinically significant by the attending physician (for example patients with pulmonary oedema and/or cardiac failure),
7. Significant hypotension (systolic blood pressure <90mmHg),
8. Known drug-eluting coronary artery stent in previous three months,
9. Known unstable angina or acute coronary syndrome in past month,
10. Known allergy to desmopressin,
11. Pregnant or breast-feeding,
12. Life expectancy less than four hours, or planned for palliative care only
13. Glasgow coma scale less than 5.
14. Use of substances that are known to induce syndrome of inappropriate ADH section (SIADH), for example, tricyclic antidepressants, selective serotonin re-uptake inhibitors, chlorpromazine and carbamazepine, may cause an additive antidiuretic effect leading to increased rick of water retention and/or hyponatremia.

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Previous 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

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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

Ireland

Italy

Malaysia

Spain

Sweden

Switzerland

Study participating centre
Luton & Dunstable University Hospital
Lewsey Rd
Luton
England
LU4 0DZ

Study participating centre
South West Acute Hospital
124 Irvinestown Road
Enniskillen
Northern Ireland
BT74 6DN

Study participating centre
Torbay Hospital
Newton Rd
Torquay
England
TQ2 7AA

Study participating centre
King's College Hospital
Denmark Hill
Brixton
London
England
SE5 9RS

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Morriston
Swansea
Wales
SA6 6NL

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby
England
DE22 3NE

Study participating centre
Yeovil Hospital
Higher Kingston
Yeovil

England
BA21 4AT

Study participating centre
Royal Victoria Hospital
274 Grosvenor Road
Belfast
Northern Ireland
BT12 6BA

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
England
HA1 3UJ

Study participating centre
Peterborough City Hospital
Edith Cavell Campus
Bretton Gate
Bretton
Peterborough
England
PE3 9GZ

Study participating centre
Arrowe Park Hospital
Arrowe Park Road
Upton
Wirral
England
CH49 5PE

Study participating centre
Salford Royal Hospital
Stott Lane
Salford
Manchester
England
M6 8HD

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle-upon-Tyne
England
NE1 4LP

Study participating centre
St George's Hospital
Blackshaw Road
London
England
SW17 0QT

Study participating centre
Royal London Hospital
Whitechapel
London
England
E1 1BB

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-Trent
England
ST4 6QG

Study participating centre
Victoria Hospital
Hayfield Road

Kirkcaldy
Scotland
KY2 5AH

Study participating centre
Musgrove Park Hospital
Parkfield Drive
Taunton
England
TA1 5DA

Study participating centre
Royal Devon and Exeter Hospital
Barrack Road
Exeter
England
EX2 5DW

Study participating centre
Gloucestershire Royal Hospital
Great Western Road
Gloucester
England
GL1 3NN

Study participating centre
Royal infirmary of Edinburgh
51 Little France Crescent
Old Dalkeith Road
Edinburgh
Scotland
EH16 4SA

Study participating centre
Royal United Hospitals
Combe Park
Bath
England
BA1 3NG

Study participating centre
West Suffolk Hospital
Hardwick Lane
Bury St. Edmunds
England
IP33 2QZ

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
England
NG5 1PB

Study participating centre
Craigavon Area Hospital
69 Lurgan Road
Portadown
Northern Ireland
BT63 5QQ

Study participating centre
Watford General Hospital
Vicarage Road
Watford
England
WD18 0HB

Study participating centre
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
England
BS10 5NB

Study participating centre
Royal Hallamshire Hospital
Glossop Road
Sheffield

England
S10 2JF

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
Leighton Hospital
Middlewich Road
Crewe
England
CW1 4QJ

Study participating centre
Royal Preston Hospital
Sharoe Green Lane North
Fulwood
Preston
England
PR2 9HT

Study participating centre
Northampton General Hospital
Cliftonville
Northampton
England
NN1 5BD

Study participating centre
The Countess of Chester Hospital
Health Park
Chester
England
CH2 1UL

Study participating centre
Glasgow Royal Infirmary
84 Castle Street
Glasgow
Scotland
G4 0SF

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

Study participating centre
Princess Royal University Hospital
Farnborough Common
Orpington
England
BR6 8ND

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
England
BD9 6RJ

Study participating centre
Southend Hospital
Prittlewell Chase
Westcliff-on-Sea
England
SS0 0RY

Study participating centre
University College London Hospital
235 Euston Road
London
England
NW1 2BU

Study participating centre
Aberdeen Royal Infirmary
Foresterhill
Aberdeen
Scotland
AB25 2ZN

Study participating centre
Kent and Canterbury Hospital
Ethelbert Rd
Canterbury
England
CT1 3NG

Study participating centre
Charing Cross Hospital
Imperial College Healthcare NHS Trust
Fulham Palace Rd
London
England
W6 8RF

Study participating centre
Daisy Hill Hospital
5 Hospital Road
Newry
Northern Ireland
BT35 8DR

Study participating centre
Royal United Hospital
Combe Park
Bath
England
BA1 3NG

Study participating centre

Queen Elizabeth Hospital
Queen Elizabeth Medical Centre
Edgbaston
Birmingham
England
B15 2TH

Study participating centre
Royal Sussex County Hospital
Eastern Road
Brighton
England
BN2 5BE

Study participating centre
Fairfield General Hospital
Rochdale Old Road
Bury
England
BL9 7TD

Study participating centre
Addenbrookes Hospital
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
England
CH2 1UL

Study participating centre
Dorset County Hospital
Williams Avenue

Dorchester
England
DT1 2JY

Study participating centre
Poole Hospital Bcsc
Poole Hospital
Longfleet Road
Poole
England
BH15 2JB

Study participating centre
University Hospital of North Durham
University Hospital of Durham
Dryburn Hospital
North Road
Durham
England
DH1 5TW

Study participating centre
Wycombe General Hospital
Queen Alexandra Road
High Wycombe
England
HP11 2TT

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
England
LS1 3EX

Study participating centre
Royal Liverpool University Hospital NHS Trust
Royal Liverpool University Hospital
Prescot Street

Liverpool
England
L7 8XP

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
The National Hospital for Neurology and Neurosurgery
Queen Square
London
England
WC1N 3BG

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone
Milton Keynes
England
MK6 5LD

Study participating centre
Queen Elizabeth Hospital
Gayton Road
King's Lynn
England
PE30 4ET

Study participating centre
Antrim Area Hospital
45 Bush Rd
Antrim
Northern Ireland
BT41 2RL

Study participating centre
Altnagelvin Area Hospital
Glenshane Road
Londonderry
Northern Ireland
BT47 6SB

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
England
NE23 6NZ

Study participating centre
Norfolk and Norwich University Hospital
Colney Lane
Colney
Norwich
England
NR4 7UY

Study participating centre
Derriford Hospital
Derriford Road
Derriford
Plymouth
England
PL6 8DH

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Study participating centre

Queens Hospital
Rom Valley Way
Romford
England
RM7 0AG

Study participating centre
Salisbury District Hospital
Odstock Road
Salisbury
England
SP2 8BJ

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
Scotland
DD1 9SY

Study participating centre
Monklands District General Hospital
Monkscourt Avenue
Airdrie
Scotland
ML6 0JS

Study participating centre
University Hospital of North Tees Tatchell Centre
University Hospital of North Tees
Hardwick Road
Stockton-on-tees
England
TS19 8PE

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

Study participating centre
Frimley Park Hospital Laboratory
Frimley Park Hospital
Portsmouth Road
Frimley
Camberley
England
GU16 7UJ

Study participating centre
Great Western Hospital Laboratory
Great Western Hospital
Marlborough Road
Swindon
England
SN3 6BB

Study participating centre
Bronglais General Hospital
Bronglais Hospital
Caradoc Road
Aberystwyth
Wales
SY23 1ER

Study participating centre
York Teaching Hospital
Wigginton Road
York
England
YO31 8HE

Study participating centre
Pinderfields Hospital
Aberford Road
Wakefield
England
WF1 4DG

Study participating centre
Epsom Hospital
Epsom General Hospital
Dorking Road
Epsom
England
KT18 7EG

Study participating centre
Lincoln County Hospital
Greetwell Road
Lincoln
England
LN2 5QY

Study participating centre
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

Study participating centre
Basildon University Hospital
Nethermayne
Basildon
England
SS16 5NL

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
England
CA2 7HY

Study participating centre
Royal Cornwall Hospital (treliske)
Treliske

Truro
England
TR1 3LJ

Study participating centre
University Hospital Coventry
Clifford Bridge Road
Coventry
England
CV2 2DX

Study participating centre
Darent Valley Hospital
Darenth Wood Road
Dartford
England
DA2 8DA

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
England
DN2 5LT

Study participating centre
Eastbourne District General Hospital
Kings Drive
Eastbourne
England
BN21 2UD

Study participating centre
Ipswich Hospital
Heath Road
Ipswich
England
IP4 5PD

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
Royal Alexandra Hospital
Marine Drive
Rhyl
Wales
LL18 3AS

Study participating centre
King's Mill Hospital
Mansfield Rd
Sutton-in-Ashfield
England
NG17 4JL

Study participating centre
Prince Philip Hospital
Bryngwynmawr
Dafen
Llanelli
Wales
SA14 8QF

Study participating centre
Royal Hampshire County Hospital
Romsey Road
Winchester
England
SO22 5DG

Study participating centre
Glan Clwd Hospital
Ysbyty Glan Clwydd
Bodelwyddan
Rhyl

Wales
LL18 5UJ

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
Wales
CF14 4XW

Study participating centre
University Hospital Hairmyres
Eaglesham Road
East Kilbride
Scotland
G75 8RG

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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
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