University of Nottingham
UK | CHINA | MALAYSIA

ISRCTN97695350

TRANEXAMIC ACID FOR INTRACEREBRAL HAEMORRHAGE: TICH-3 TRIAL

WARD TRAINING

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On behalf TICH-3 Trial Team

Final v2.0 23/04/2024

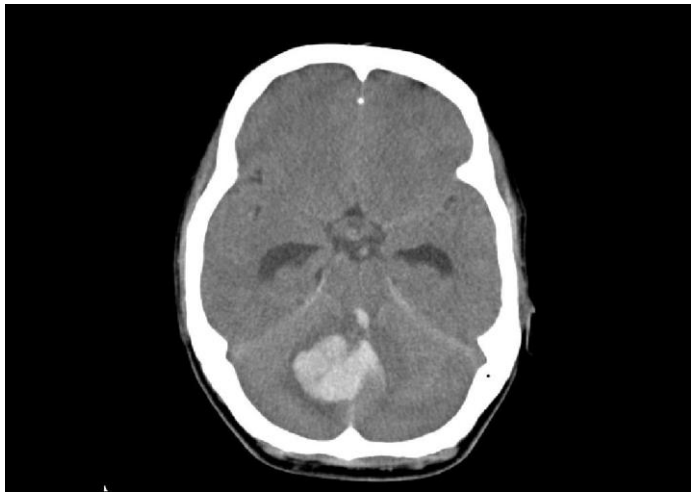
Introduction

- TICH-3 is a double-blinded, randomised study recruiting patients with confirmed Intracerebral Haemorrhage (ICH)
- Participants must be randomised within 4.5 hours of stroke onset (or symptom discovery following wake-up)
- Participants will also receive usual Standard of Care e.g. blood pressure lowering treatment, DOAC reversal with PCC, referral to neurosurgery

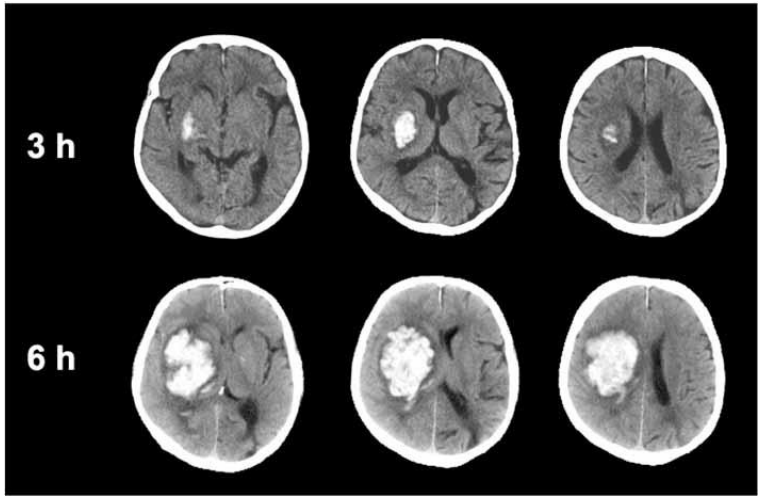
Rationale

- 1.7 million strokes worldwide per year with a mortality of over 40%
- 10,000+ people suffered an Intracerebral Haemorrhage (ICH) last year in England
- There is no effective drug treatment to stop continued bleeding (haematoma growth) after ICH
- Tranexamic acid (TXA) reduces bleeding and death in other emergency bleeding conditions

TICH-3: does giving tranexamic acid early after ICH prevent haematoma expansion and reduce death and disability



Case courtesy of Dr Farzad Pirzad, Radiopaedia.org, rID: 9620



Bornes, Troy & Butcher, Ken. (2009). Management of Hypertension in the Acute Phase of Stroke. Current Hypertension Reviews. 5.

Streamlined recruitment process

CT/MRI scan shows bleeding and is within 4.5 hours of symptom discovery

1. **Confirm eligibility** can be completed by any clinician they do not need to be on the TICH-3 delegation log
2. **Take initial oral enrolment consent the** process of eligibility and consent just needs to be documented in the medical record. We also allow remote recruitment over phone/telemedicine. If no relatives, then ask an independent doctor and use brief consent form to document.
   - *Members of research team taking consent must be appropriately trained and authorised on the TICH-3 deleagtion log with code J applied (enrolment consent for CTIMPs)*
   - ***If research team are not available** participant can be consented by a member of clinical team and documented via the eligibility checklist and enrolment form (SA_06_24 & MA_24_24)*
3. **Lowest numbered TICH-3 treatment pack** is prescribed and administered by appropriately trained staff (they do not need to be on the delegation log or GCP trained)
4. **Complete QR code recruitment alert** this is within each treatment pack and can be completed by anyone (do not need to be on delegation log, no logins required to complete the form to alert the team a recruitment has taken place)
5. **When the research team is next on site** you will see the recruitment alert in your emails to know a participant was recruited and then you would find the participant to take the follow-on written consent, add participant to website and begin data entry

PRAGMATIC METHODS ALLOWS FOR STREAMLINED RECRUITMENT OUT OF HOURS

TICH-3 Eligibility Criteria

Inclusion criteria

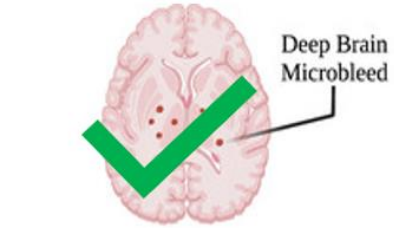
- Spontaneous ICH (confirmed on brain imaging) < 4.5 hours of onset

It is not necessary to exclude underlying vascular lesions – but if they are known please do not include.

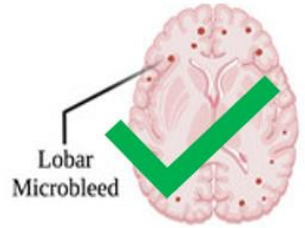
IMP treatment should be started within the 4.5 hours inclusion window.

Exclusion criteria

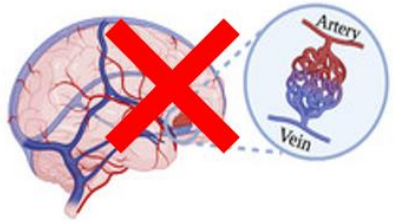
- Known indication for TXA treatment (e.g. traumatic brain injury) *or* contra-indication for TXA treatment (e.g. active seizures) *in view of treating physician*
- Patient known to be taking therapeutic anticoagulation with warfarin or low molecular weight heparin at time of enrolment. **(DOAC is permitted)**
- Massive ICH (usually when haematoma volume > 60ml HV – **only estimation is needed (+/- 10%)**
- Severe coma, Glasgow Coma Scale <5, palliative (end of life) care



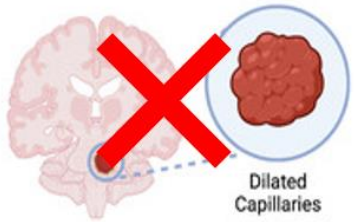
Hypertension Microangiopathy



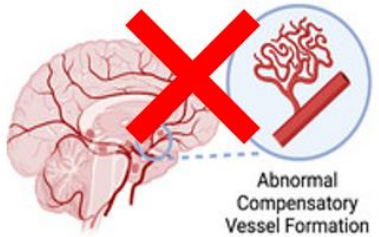
Cerebral Amyloid Angiopathy



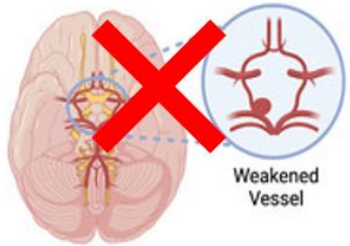
Arteriovenous Malformation



Cavernous Angioma



Moyamoya Disease



Aneurysm

Emergency Consent Process

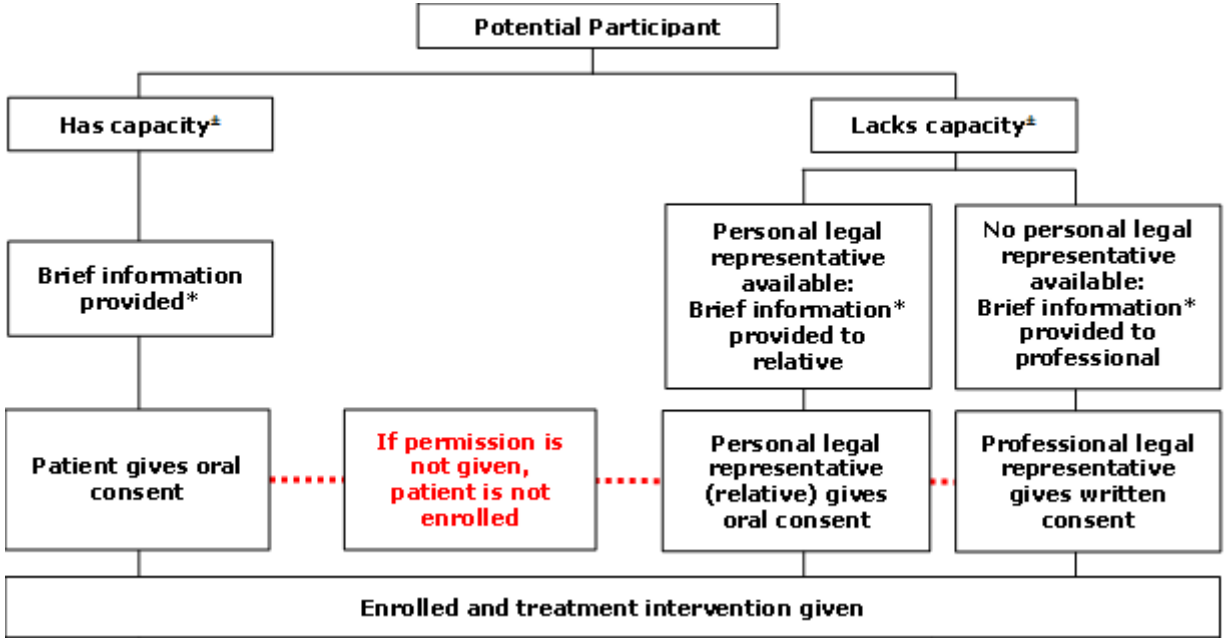
Rapid consent process, initial verbal consent

Full informed written consent to be obtained later after administration of IMP

Hierarchy approach in UK

1. Patient has capacity – gives oral consent
2. Patient does not have capacity – relative or close friend likely to know patient wishes provides oral consent
3. Patient does not have capacity and no relatives available – independent doctor provides written consent

- Oral consent can be given over the telephone and then follow-on written consent obtained when relative is on site
- A delegated doctor may assess the patient via telemedicine to obtain verbal consent.
- Medical record must document that the patient meets TICH-3 eligibility criteria and oral consent was given



± Assessment of capacity is the responsibility of the treating physician

Members of research team taking consent must be appropriately trained and authorised on the TICH-3 deleagtion log

If research team are not available participant can be consented by a member of clinical team and documented via the eligibility checklist and enrolment form (SA_06_24)

Professional legal representative enrolment consent by an independent doctor

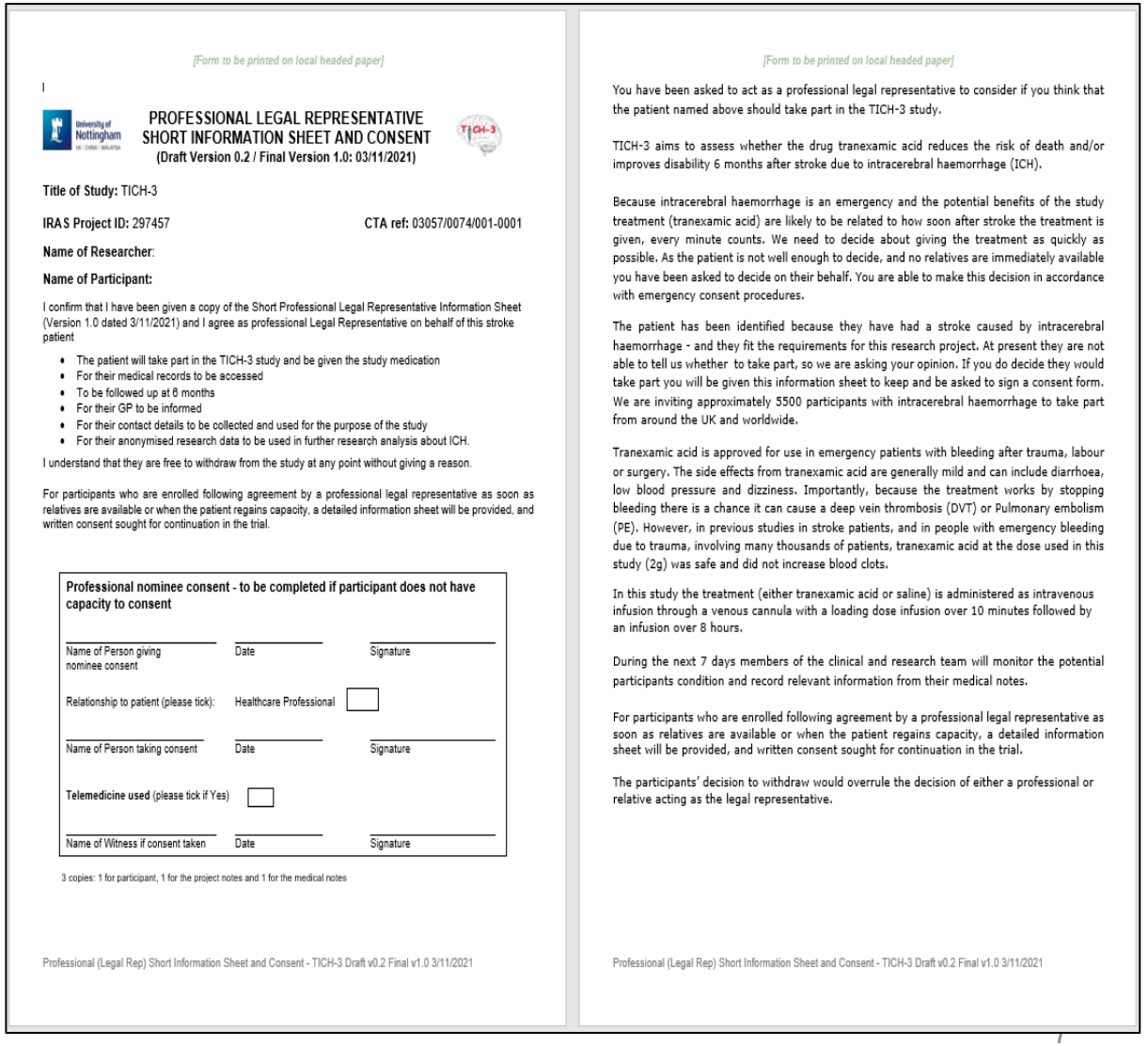
If patient does not have capacity to consent and no relatives are contactable then an independent doctor can act as professional legal representative for the patient.

Enrolment consent by independent doctor

Short Information Sheet and Consent form should be used (pictured to the right). In this scenario the professional legal representative enrolment consent is handwritten.

Informing relatives

The clinician at site has full responsibility for informing relatives of participant when professional legal representative consent has taken place. In event of a patient dying after being enrolled by a professional legal representative but before relatives can be contacted the clinical team should inform the relatives of the patient's involvement in the study and provide information about the study.



[Form to be printed on local headed paper]

I

PROFESSIONAL LEGAL REPRESENTATIVE
SHORT INFORMATION SHEET AND CONSENT
(Draft Version 0.2 / Final Version 1.0: 03/11/2021)

Title of Study: TICH-3

IRAS Project ID: 297457 **CTA ref:** 03057/0074/001-0001

Name of Researcher:

Name of Participant:

I confirm that I have been given a copy of the Short Professional Legal Representative Information Sheet (Version 1.0 dated 3/11/2021) and I agree as professional Legal Representative on behalf of this stroke patient

- The patient will take part in the TICH-3 study and be given the study medication
- For their medical records to be accessed
- To be followed up at 6 months
- For their GP to be informed
- For their contact details to be collected and used for the purpose of the study
- For their anonymised research data to be used in further research analysis about ICH.

I understand that they are free to withdraw from the study at any point without giving a reason.

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.

Professional nominee consent - to be completed if participant does not have capacity to consent

Name of Person giving nominee consent | Date | Signature

Relationship to patient (please tick): Healthcare Professional ☐

Name of Person taking consent | Date | Signature

Telemedicine used (please tick if Yes) ☐

Name of Witness if consent taken | Date | Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

Professional (Legal Rep) Short Information Sheet and Consent - TICH-3 Draft v0.2 Final v1.0 3/11/2021

[Form to be printed on local headed paper]

You have been asked to act as a professional legal representative to consider if you think that the patient named above 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).

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. As the patient is 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.

The patient has been identified because they have had a stroke caused by intracerebral haemorrhage - and they fit the requirements for this research project. At present they are not able to tell us whether to take part, so we are asking your opinion. 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.

Tranexamic acid is approved for use in emergency patients with bleeding after trauma, labour or surgery. The side effects from tranexamic acid are generally mild and can include diarrhoea, low blood pressure and dizziness. Importantly, because the treatment works by stopping bleeding there is a chance it can cause a deep vein thrombosis (DVT) or Pulmonary embolism (PE). However, in previous studies in stroke patients, and in people with emergency bleeding due to trauma, involving many thousands of patients, tranexamic acid at the dose used in this study (2g) was safe and did not increase blood clots.

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.

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.

The participants' decision to withdraw would overrule the decision of either a professional or relative acting as the legal representative.

Professional (Legal Rep) Short Information Sheet and Consent - TICH-3 Draft v0.2 Final v1.0 3/11/2021

Enrolment consent when research team are not available

- We have received ethical approval to implement the eligibility checklist and enrolment form (SA_06_24 and MA_24_24)
- This form allow clinicians at the local site that are not on the TICH-3 delegation log and may not be GCP trained to be fully informed of the TICH-3 trial by reading the synopsis on the eligibility checklist and enrolment form and then using the checklist to assess their eligibility. If eligible the clinician will discuss with the potential participant and if consent is taken, they will be enrolled into the trial and will receive the trial treatment.
- All study materials, including protocol and related documents, will be available online and there will be a 24-hour telephone service, supported by medical consultant staff and trained coordinating centre research staff.
- Within each treatment pack is a prescribing and administration guide, the team member on site completes a recruitment alert (the team member does not need to be on the delegation log or have a log in for the TICH-3 website to complete) which emails all team members on the sites delegation log and the coordinating centre that a recruitment has taken place so that when the delegated research team are next on site they can follow up the participant as normal and obtain the follow on written consent.
- This approach is to ensure participants do not miss out on the opportunity to participate in the trial because they present when the research team are not present, particularly in smaller hospitals or outside working hours. This approach has the support of our stroke survivor group, and will be monitored closely, and any protocol violations reported to sponsor and the trial steering committee.
- We have worked very closely with our PPI group to develop and co-design this approach which we believe is proportional to risk benefit; tranexamic acid is a relatively low risk intervention, with an established safety profile, in the setting of a time critical medical emergency, ICH is a devastating condition with no effective drug treatment available.

Eligibility checklist and enrolment form FAQs (SA_06_24 and MA_24_24)

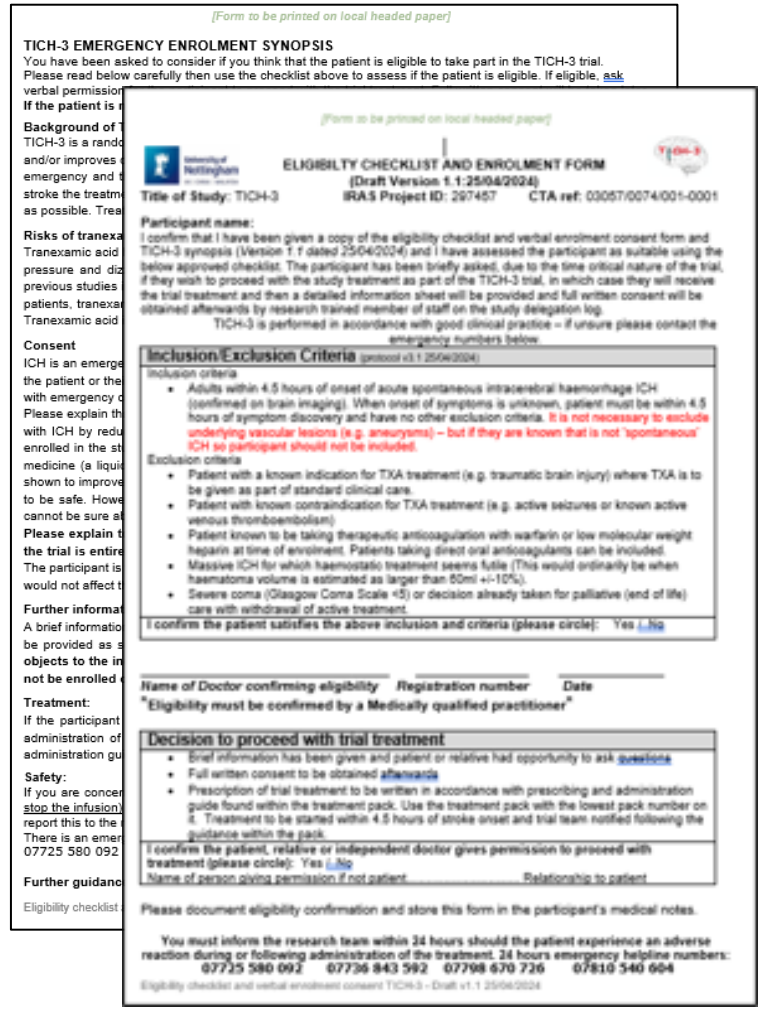
When can this method of consent be used? This is ONLY to be used when the delegated research team are not available to consent participants into TICH-3.

Who can take consent via this method? Site PI may delegate enrolment and administration of the IMP to appropriately trained members of the treating clinical team (not on TICH-3 delegation log, does not need to be GCP trained or have CV on file). There is no minimum grade doctor. Eligibility must be assessed by a medically qualified practitioner under the clinical trial regulations.

How is this consent process documented? This would be facilitated and documented by the use of an approved study synopsis, eligibility checklist and enrolment form which then would be stored in the participant's medical record.

What happens after this consent? Participant will be enrolled, and treatment administered by appropriate trained team members at the site. Full written consent would then be obtained as soon as practicable by a member of the local research team who is GCP trained and delegated the responsibility on the study delegation log.

Alternative text: screenshot of the eligibility checklist and enrolment form



[Form to be printed on local headed paper]

TICH-3 EMERGENCY ENROLMENT SYNOPSIS

You have been asked to consider if you think that the patient is eligible to take part in the TICH-3 trial. Please read below carefully then use the checklist above to assess if the patient is eligible. If eligible, ask verbal permission

If the patient is

Background of

TICH-3 is a rando and/or improves emergency and stroke the treatm as possible. Trea

Risks of tranexa

Tranexamic acid pressure and diz previous studies patients, tranexa Tranexamic acid

Consent

ICH is an emerge the patient or the with emergency Please explain th with ICH by redu enrolled in the st medicine (a liqui shown to improve to be safe. Howe cannot be sure al

Please explain t

the trial is entire

The participant is would not affect t

Further informat

A brief informatio be provided as s

objects to the in

not be enrolled

Treatment:

If the participant administration of administration gu

Safety:

If you are concer stop the infusion) report this to the There is an emer 07725 580 092

Further guidanc

Eligibility checklist

[Form to be printed on local headed paper]

ELIGIBILTY CHECKLIST AND ENROLMENT FORM

(Draft Version 1.1 25/04/2024)

Title of Study: TICH-3 IRAS Project ID: 297457 CTA ref: 03057/0074/001-0001

Participant name:

I confirm that I have been given a copy of the eligibility checklist and verbal enrolment consent form and TICH-3 synopsis (Version 1.1 dated 25/04/2024) and I have assessed the participant as suitable using the below approved checklist. The participant has been briefly asked, due to the time critical nature of the trial, if they wish to proceed with the study treatment as part of the TICH-3 trial, in which case they will receive the trial treatment and then a detailed information sheet will be provided and full written consent will be obtained afterwards by research trained member of staff on the study delegation log.

TICH-3 is performed in accordance with good clinical practice – if unsure please contact the emergency numbers below

Inclusion/Exclusion Criteria (protocol v3.1 25/04/2024)

Inclusion criteria

- Adults within 4.5 hours of onset of acute spontaneous intracerebral haemorrhage ICH (confirmed on brain imaging). When onset of symptoms is unknown, patient must be within 4.5 hours of symptom discovery and have no other exclusion criteria. It is not necessary to exclude underlying vascular lesions (e.g. aneurysms) – but if they are known that is not 'spontaneous' ICH so participant should not be included.

Exclusion criteria

- Patient with a known indication for TXA treatment (e.g. traumatic brain injury) where TXA is to be given as part of standard clinical care.
- Patient with known contraindication for TXA treatment (e.g. active seizures or known active venous thromboembolism)
- Patient known to be taking therapeutic anticoagulation with warfarin or low molecular weight heparin at time of enrolment. Patients taking direct oral anticoagulants can be included.
- Massive ICH for which haemostatic treatment seems futile (This would ordinarily be when haematoma volume is estimated as larger than 60ml +/-10%).
- Severe coma (Glasgow Coma Scale <5) or decision already taken for palliative (end of life) care with withdrawal of active treatment.

I confirm the patient satisfies the above inclusion and criteria (please circle): Yes / No

Name of Doctor confirming eligibility Registration number Date

"Eligibility must be confirmed by a Medically qualified practitioner"

Decision to proceed with trial treatment

- Brief information has been given and patient or relative had opportunity to ask questions
- Full written consent to be obtained afterwards
- Prescription of trial treatment to be written in accordance with prescribing and administration guide found within the treatment pack. Use the treatment pack with the lowest pack number on it. Treatment to be started within 4.5 hours of stroke onset and trial team notified following the guidance within the pack.

I confirm the patient, relative or independent doctor gives permission to proceed with treatment (please circle): Yes / No

Name of person giving permission if not patient Relationship to patient

Please document eligibility confirmation and store this form in the participant's medical notes.

You must inform the research team within 24 hours should the patient experience an adverse reaction during or following administration of the treatment. 24 hours emergency helpline numbers: 07725 580 092 07736 843 592 07798 670 726 07810 540 604

Eligibility checklist and verbal enrolment consent TICH-3 - Draft v1.1 25/04/2024

Consent process flowchart

Trained staff on TICH-3 delegation log available

Verbal consent obtained by trained staff on TICH-3 delegation log (code J)

No trained staff on delegation log, that can take enrolment consent, available

Clinical team use eligibility checklist and enrolment form

Open next lowest numbered treatment pack to randomise.

Prescribe and administer trial treatment.

QR code recruitment alert.

Document in medical notes eligibility and consent process.

When research team next on site

Follow on written consent obtained by trained staff on TICH-3 delegation log (code Z)

Add participant to TICH-3

Add a new participant

Upload consent form to secure vault.

Collect contact details and add to secure vault.

Begin eCRF data collection.

TICH-3 Treatment Packs

- Temperature monitoring is not required. The packs will be stored at room temperature and protected from excessive heat and freezing
- TICH-3 treatment packs contain 4 ampoules: Tranexamic Acid **OR** Sodium Chloride (placebo)
- The IMP is stored in a secure, limited access storage area, this could be in the A&E, stroke ward or thrombolysis bag
- Ensure all members of the local team are aware of where the IMP and related documents (consent forms/PIS) are stored
- Local site is responsible for the accountability and monitoring of the IMP
- Research coordinators will carry out checks monthly to ensure all treatment packs are sealed and accounted for
- TICH-3 drug should **NEVER** be given to patients that are not enrolled in to the TICH-3 trial
- To randomise open the next lowest numbered treatment pack

Prescribing and Administering the IMP

Prescribing the IMP

Investigational medicinal product (IMP) is prescribed on the participant's inpatient treatment chart by appropriately trained medical practitioners or health care professionals who are non-medical or independent prescribers. It is acceptable to use a handwritten or electronic prescribing system for IMP prescribing.
Do not need to be on delegation log or GCP trained to prescribe.

Prescribe (write in participants drug chart):

TICH-3 - TRIAL Pack Number XXXXX

TRANEXAMIC ACID OR PLACEBO

2 ampoules (10ml) added to 100ml Sodium Chloride Injection 0.9% administered as an IV infusion over 10 minutes.

AND

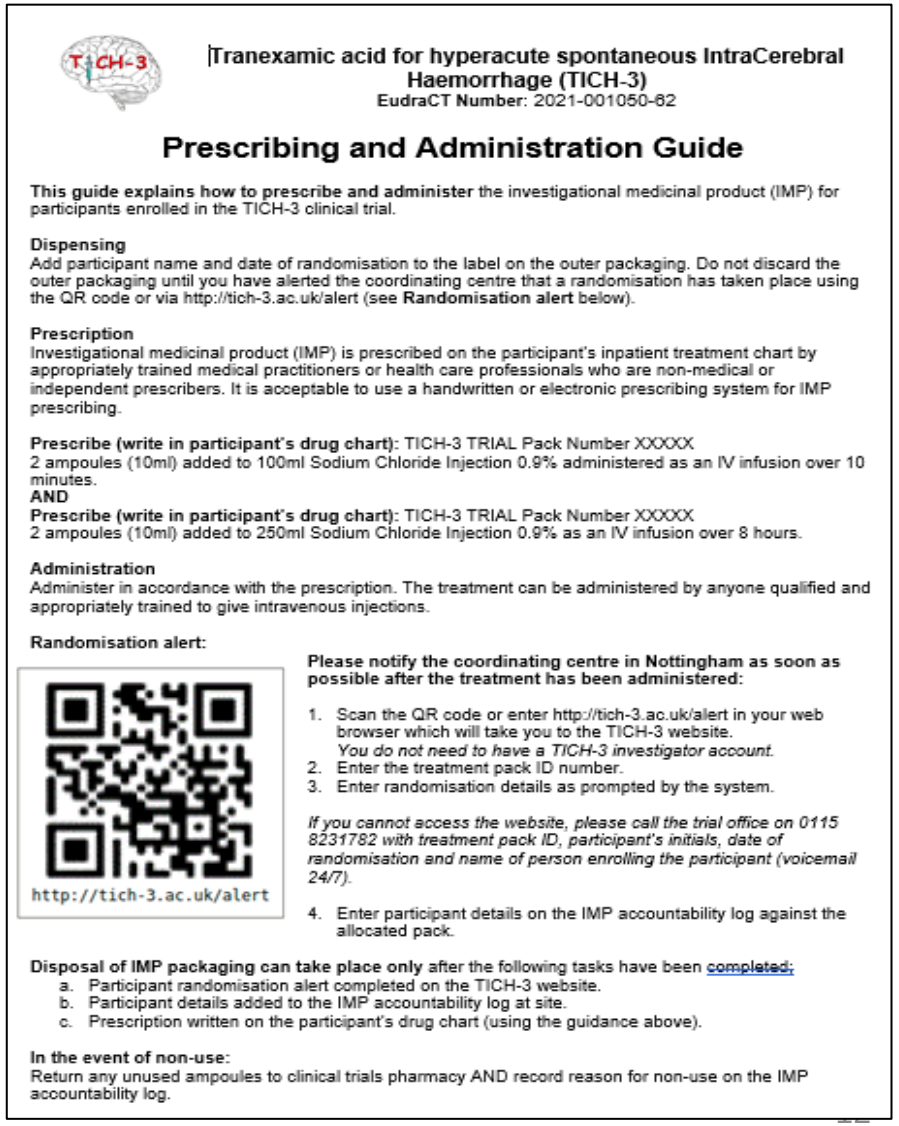
TICH-3 TRIAL Pack Number XXXXX

TRANEXAMIC ACID OR PLACEBO

2 ampoules (10ml) added to 250ml Sodium Chloride Injection 0.9% as an IV infusion over 8 hours.

Administering the IMP

Administer in accordance with the prescription. The treatment can be administered by anyone qualified and appropriately trained to give intravenous injections. ***Do not need to be on delegation log or GCP trained to administer.***



Tranexamic acid for hyperacute spontaneous IntraCerebral Haemorrhage (TICH-3)
EudraCT Number: 2021-001050-62

Prescribing and Administration Guide

This guide explains how to prescribe and administer the investigational medicinal product (IMP) for participants enrolled in the TICH-3 clinical trial.

Dispensing
Add participant name and date of randomisation to the label on the outer packaging. Do not discard the outer packaging until you have alerted the coordinating centre that a randomisation has taken place using the QR code or via http://tich-3.ac.uk/alert (see **Randomisation alert** below).

Prescription
Investigational medicinal product (IMP) is prescribed on the participant's inpatient treatment chart by appropriately trained medical practitioners or health care professionals who are non-medical or independent prescribers. It is acceptable to use a handwritten or electronic prescribing system for IMP prescribing.

Prescribe (write in participant's drug chart): TICH-3 TRIAL Pack Number XXXXX
2 ampoules (10ml) added to 100ml Sodium Chloride Injection 0.9% administered as an IV infusion over 10 minutes.
AND
Prescribe (write in participant's drug chart): TICH-3 TRIAL Pack Number XXXXX
2 ampoules (10ml) added to 250ml Sodium Chloride Injection 0.9% as an IV infusion over 8 hours.

Administration
Administer in accordance with the prescription. The treatment can be administered by anyone qualified and appropriately trained to give intravenous injections.

Randomisation alert:

http://tich-3.ac.uk/alert

Please notify the coordinating centre in Nottingham as soon as possible after the treatment has been administered:

1. Scan the QR code or enter http://tich-3.ac.uk/alert in your web browser which will take you to the TICH-3 website.
   You do not need to have a TICH-3 investigator account.
2. Enter the treatment pack ID number.
3. Enter randomisation details as prompted by the system.

If you cannot access the website, please call the trial office on 0115 8231782 with treatment pack ID, participant's initials, date of randomisation and name of person enrolling the participant (voicemail 24/7).

4. Enter participant details on the IMP accountability log against the allocated pack.

Disposal of IMP packaging can take place only after the following tasks have been completed:
a. Participant randomisation alert completed on the TICH-3 website.
b. Participant details added to the IMP accountability log at site.
c. Prescription written on the participant's drug chart (using the guidance above).

In the event of non-use:
Return any unused ampoules to clinical trials pharmacy AND record reason for non-use on the IMP accountability log.

Randomisation Alert

1. Enter the treatment pack ID (pack number), participant initials and their own initials to alert the coordinating centre to a new randomisation.

SCAN
QR CODE

http://tich-3.ac.uk/

Let us know about a new TICH-3 participant

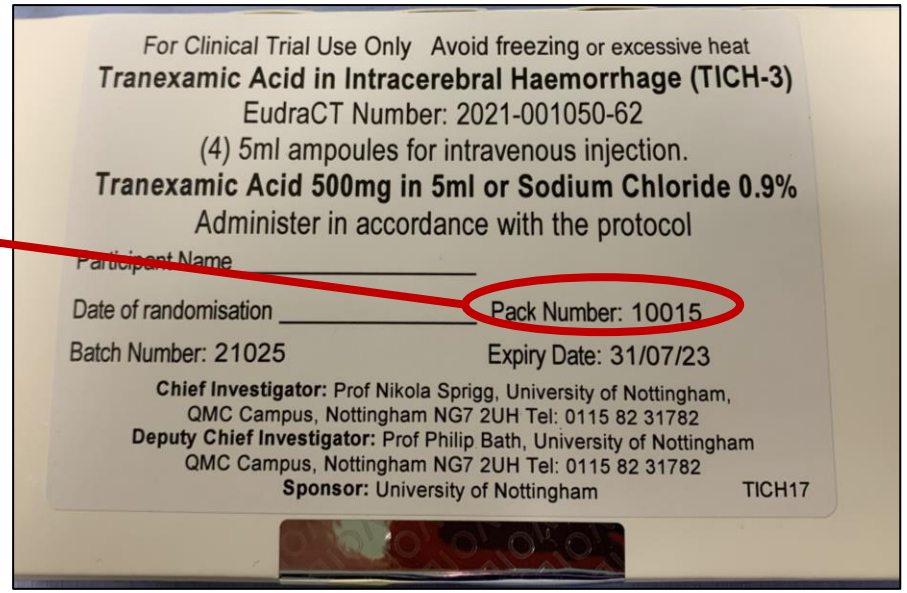
Treatment pack ID:

Participant's initials:
(2 or 3 letters)

Your initials:
(2 or 3 letters)

Submit

For initials, please use first letters from forename then surname and enter a dash (-) if no middle initial



2. Investigator will then confirm that the participant was randomised at the hospital shown in the alert box.

Please confirm that the TICH-3 participant was randomised at the hospital shown below.

Centre ID: **C001**

City/name: **NOTTINGHAM, Nottingham DEMO Hospital**

Country: **United Kingdom**

Confirm Cancel

Broken vials:

Broken prior to randomisation e.g. upon receipt in pharmacy

✓Inform the Nottingham coordinating centre and dispose of the pack(s) in accordance with WPD (Destruction of IMP).

Broken after randomisation, **before treatment**:

✓Disregard this pack and use the lowest treatment pack ID that is available at your centre

Broken during treatment i.e. Bolus given but infusion vial breaks:

✓Administer as much drug as possible

✓Record on day 7 form that participant does not receive all of the randomised treatment as per protocol and explain why

x Do not open another treatment pack

Always record broken vials on the inventory or accountability log as appropriate

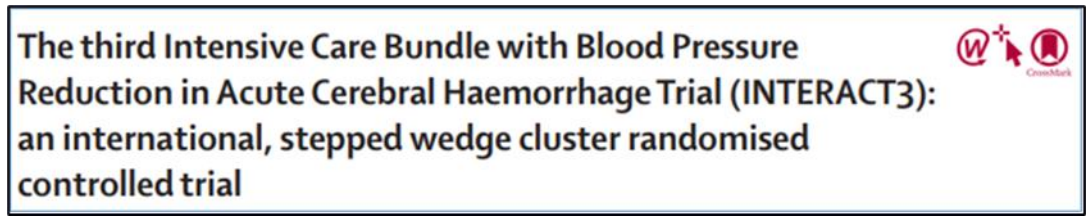
Standard of care for ICH – ABC ICH bundle of care

- All participants should receive standard care for ICH as per the local clinical pathway and guidelines. This is likely to include referral to a stroke unit and components of ABC-ICH

✓ **A**nticoagulation reversal

✓ **B**lood pressure lowering as per clinical guidelines[1] target
For patients with BP 150-220mmHg aim for BP 130-140mmg
x Do not use the same cannula for study drug infusion and blood pressure lowering infusions– need separate IV access line

aiming for a target of BP< 140mmHg as per clinical guidelines, supported by the recent INTERACT -3 Results https://doi.org/10.1016/S0140-6736(23)00806-1


The third Intensive Care Bundle with Blood Pressure Reduction in Acute Cerebral Haemorrhage Trial (INTERACT3): an international, stepped wedge cluster randomised controlled trial

✓ **C**onsideration of referral to neurosurgery or critical care if appropriate

✓ Prophylaxis of venous thromboembolism with intermittent compression stockings

Please note tranexamic acid is not standard of care for spontaneous ICH

1: https://www.nice.org.uk/guidance/ng128/chapter/Recommendations

What to do in Case of Emergency

Safety events during the infusion

If seizure, thrombosis or arterial occlusion occurs during infusion, the infusion must be stopped immediately. This will be recorded as part of the trial documentation and safety monitoring.

- Try to contact the clinician that enrolled the patient if available

- If TICH-3 trained investigators are not available, the emergency numbers should be used for further guidance. Please make sure these numbers are noted down with the TICH-3 treatment packs for if required in an emergency.

> For urgent medical enquiries (including unblinding), and for randomisation problems, you can contact the following emergency mobile numbers. Please ensure that you have these written down.
>
> +44 (0)7725 580 092 +44 (0)7736 843 592
>
> +44 (0)7798 670 726 +44 (0)7810 540 604

- For non-emergency queries the TICH-3 office can also be contacted on 0115 823 1782 between 8am and 5pm Monday – Friday

Co-enrolment with TICH-3

We are open to co-enrolment however we need to have a co-enrolment agreement in place with other interventional studies before co-enrolment is permitted.

There is a co-enrolment log on the TICH-3 documents page, please check this to review if co-enrolment with the respective trial is permitted
https://stroke.nottingham.ac.uk/sif/docs/?sid=TICH-3

If the trial is not listed on listed please contact us so we can start the process to get a co-enrolment agreement in place.

CO-ENROLMENT MUST NOT TAKE PLACE UNLESS THERE IS AN AGREEMENT IN PLACE

Further Information and Getting Involved

- The NIHR provides free Good Clinical Practice training and further information
- You can self-register using your NHS email via the this link:

  https://portal.nihr.ac.uk/register?app=LMS

- The TICH-3 documents page provides further guidance documents https://stroke.nottingham.ac.uk/sif/docs/?sid=TICH-3

- Contact your local Stroke Research Team if you are interested in becoming a TICH-3 investigator

University of Nottingham Trial Team

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Trial Coordinating Centre contact information:

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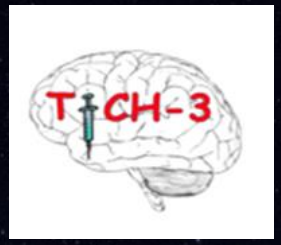
TICH-3@nottingham.ac.uk

University of Nottingham
UK | CHINA | MALAYSIA



THANK YOU!

Any questions?

TICH-3@nottingham.ac.uk

Audit list of updates to training presentations

Previous version 1.1 08/03/2024

Added information new co-enrolment agreement process

Previous version 2.2 23/04/2024

- Slide Out of hours recruitment clarified members of research team must be delegated code J on delegation log, if research team not available a member of clinical team can take consent and document using the eligibility checklist and enrolment form. Combined streamlined process slide/out of hours slide/remote recruitment process slide.
- Edited Emergency Consent Process slide that person taking consent code J if research team or if not available medic can use eligibility checklist and enrolment form
- Added eligibility checklist and enrolment form slide and FAQ slide
- Added out of hours recruitment slide

This version 2.1 17/12/2024

- Updated SAE review for local PI that now is electronic
- Updated co-enrolment slide, removing specific trial details and to refer to the log so that the training slides don't have to be updated every time a co-enrolment agreement is fully executed
- Updated contact details