University of Nottingham
UK | CHINA | MALAYSIA

ISRCTN97695350

TRANEXAMIC ACID FOR INTRACEREBRAL HAEMORRHAGE: TICH-3 TRIAL

UK UPDATE MEETING

Professor Nikola Sprigg and Brittany Hare

On behalf TICH-3 Trial Team

Thursday 13h June 2024

Agenda

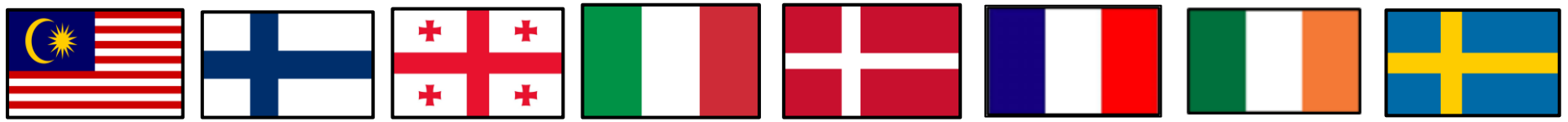
1. Recruitment update
2. Protocol amendment SA06 & MA24 APPROVED
3. Updated document – eligibility checklist (optional document)
4. Data corrections
5. Safety Events, SARS and SUSARS
6. Co-enrolment with TICH-3
7. Protocol compliance
8. ICH update from ESOC
9. Upcoming events
10. Thank you
11. Questions?

UK Recruitment Update

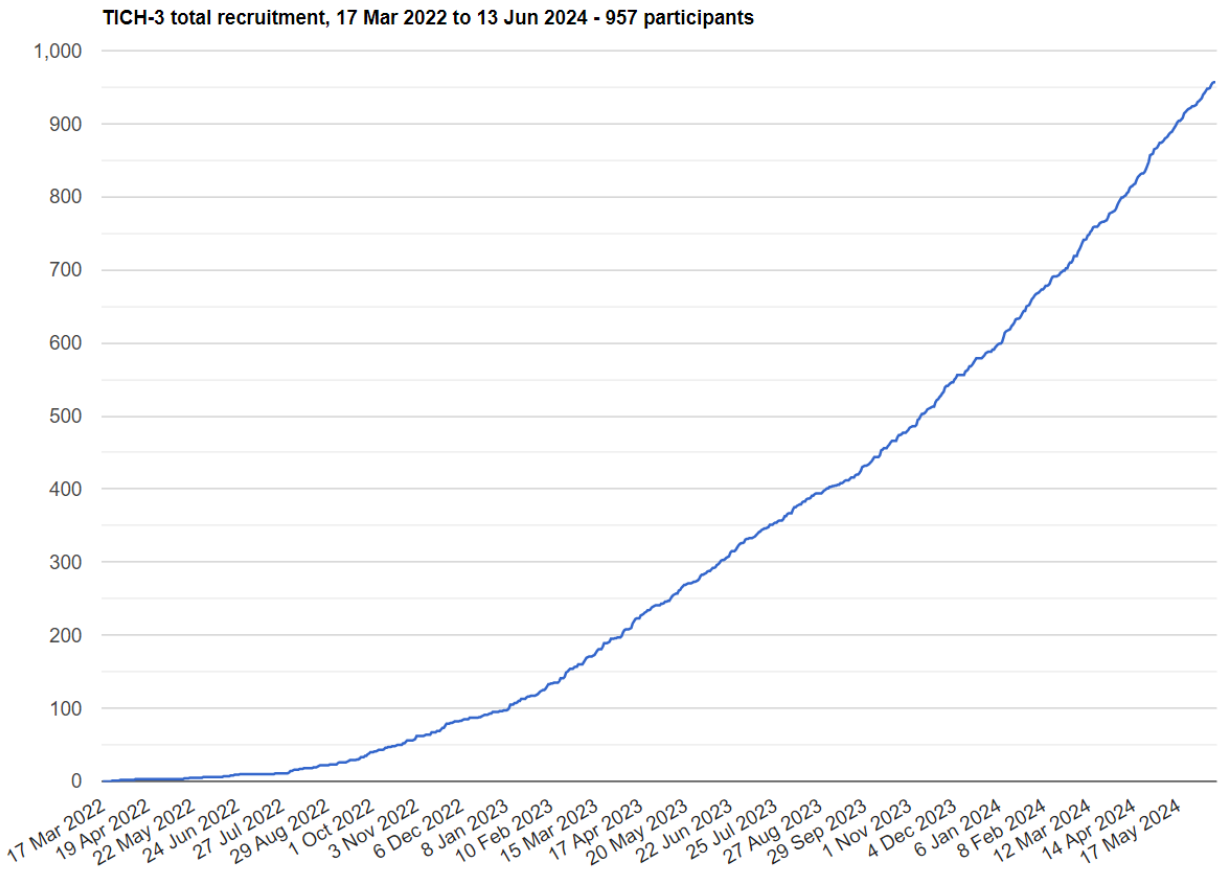
Site Status *(updated 13/06/2024)*	No.
Sites open to recruitment	71
Recruited *(597 participants in total)*	65
Not recruited	6
In set up	2
Initial feasibility assessments	7
Declined for now (capacity issues)	6
Withdrawn	9

Alternative text: map of UK with the UK sites active for recruitment plotted

International Recruitment Update



(updated 13/06/2024)	Sites open	Recruited
Malaysia	14/14	191
Finland	1/1	50
Georgia	3/4	42
Denmark	1/4	24
Italy	4/25	19
France	11/16	33
Ireland	1/6	2
Sweden	1/3	0
Totals	36/73	361



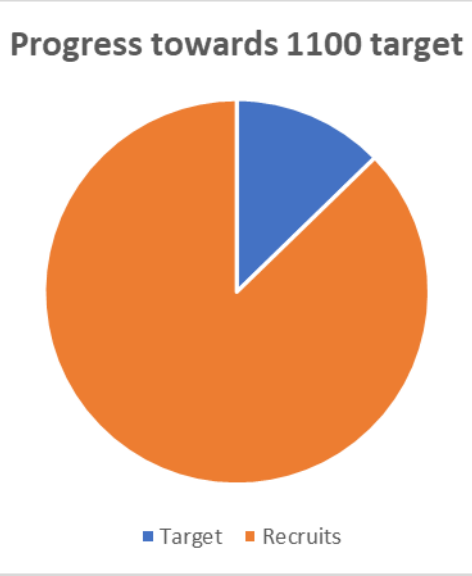
Combined total recruitment: 958

We have reached over 950 participants!

Thank you for all your recruitment into the TICH-3 trial, we couldn't do it without you!

Pilot progression review: updated targets

- Data to be reviewed again end of August 2024
- HTA 1,100 ppts and 120 sites (75 UK) by 31/08/2024



We are 87.27% towards the target participant recruitment

Project Month	Month	New Target	Actual No. sites
29	September-23	55	57
30	October-23	N/A	57
31	November 23	60	60
32	December 23	62	63
33	January 24	64	66
34	February 24	65	67
35	March 24	66	70
36	April 24	67	71
37	May 24	68	71
38	June 24	70	
39	July 24	73	
40	August 24	75	

Protocol amendment SA_06_24 and MA_24_24

- SA_06_24 approved 22/04/2024 and MA_24_24 approved 26/04/2024

Please note SA_06_24 was approved for Protocol Final v3.0 28/02/2024 and then a minor amendment was submitted straight away under MHRA guidance to correct a few typographical errors. MA_24_24 was approved for Protocol Final v3.1 25/04/2024.

The protocol that sites must adhere by is now TICH-3 Protocol Final v3.1 25/04/2024.

Notification email to sites 09/05/2024.

<u>Summary of changes</u>

The aim of this protocol amendment is fivefold

1. To capture participant co-morbidity using the Clinical Frailty Score (CFS)
2. To measure post stroke fatigue using Fatigue Severity Scale (FSS-7)
3. To streamline the health economics/resource use form to improve data completion for patients
4. To add an eligibility checklist to facilitate enrolment when no one on delegation log available
5. Took this opportunity to make some minor text changes to the protocol, including updating the literature review and adding points of clarity to assist investigators

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 medics 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)

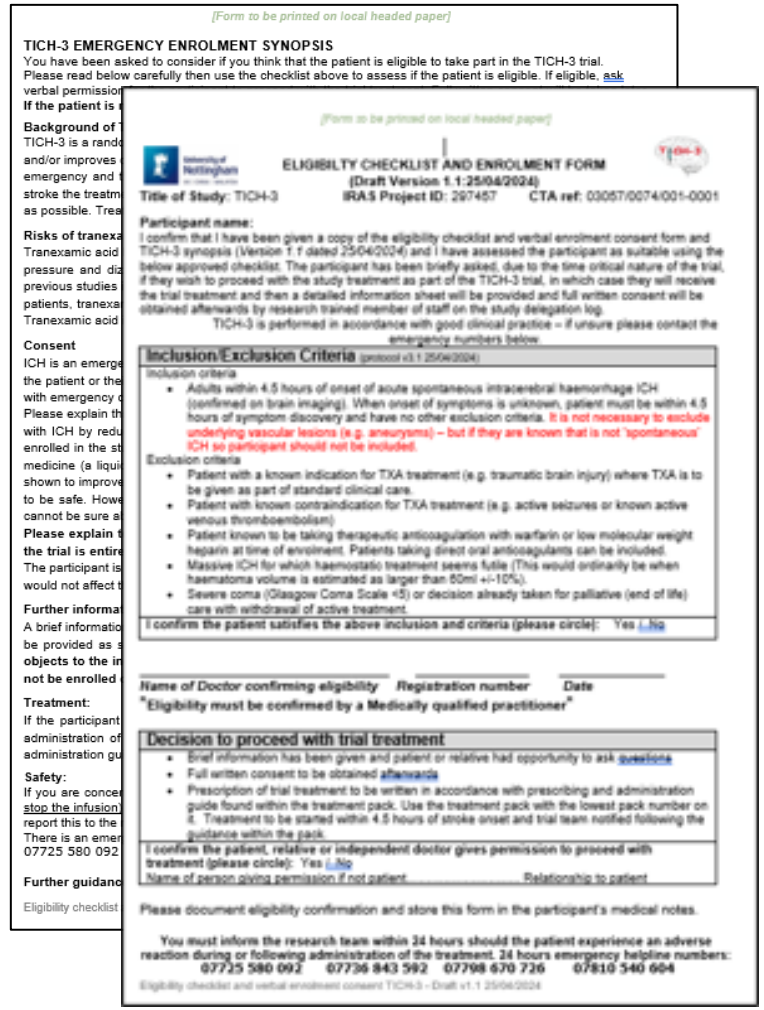
When can this method of consent be used? This is ONLY to be used when the delegated research team are not available to consent participants into TICH-3.

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



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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

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Further guidanc

Eligibility checklist

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University of Nottingham

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

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

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 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.

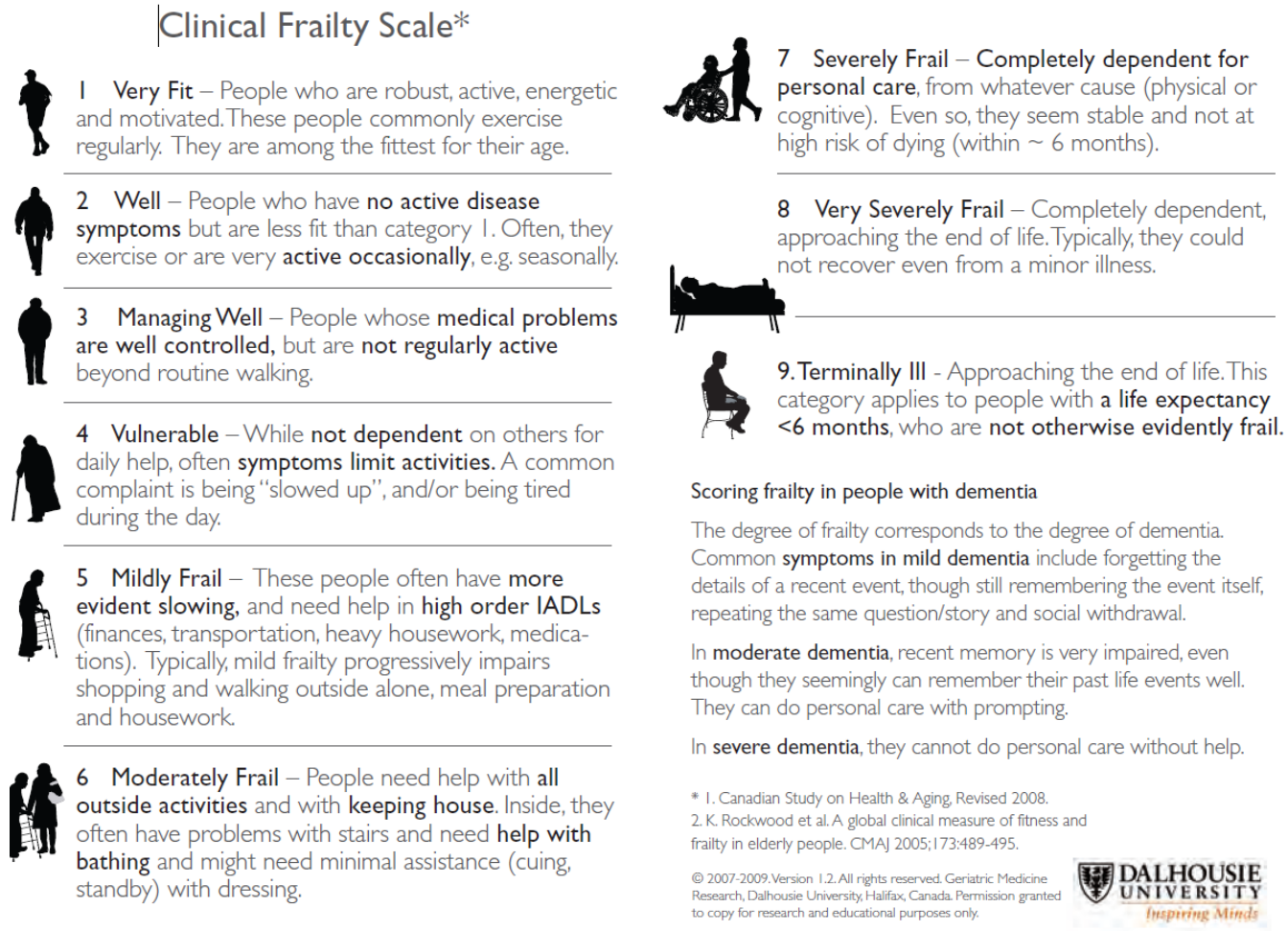
Collect contact details and add to secure vault.

Begin eCRF data collection.

Protocol amendment – changes at sites

1. Collect pre-stroke baseline CFS

- This scale will be added to the enrolment eCRF
- You do not need to backfill data for existing participants but please collect for future participants once implemented



Clinical Frailty Scale*

1 **Very Fit** – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

2 **Well** – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.

3 **Managing Well** – People whose **medical problems are well controlled,** but are **not regularly active** beyond routine walking.

4 **Vulnerable** – While **not dependent** on others for daily help, often **symptoms limit activities.** A common complaint is being "slowed up", and/or being tired during the day.

5 **Mildly Frail** – These people often have **more evident slowing,** and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

6 **Moderately Frail** – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.

7 **Severely Frail** – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

8 **Very Severely Frail** – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

9. **Terminally Ill** - Approaching the end of life. This category applies to people with **a life expectancy <6 months**, who are **not otherwise evidently frail.**

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

* 1. Canadian Study on Health & Aging, Revised 2008.
2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

DALHOUSIE UNIVERSITY *Inspiring Minds*

Alternative text: validated CFS scale image of scoring values

Enrolment form eCRF changes SA_06_24

Current enrolment eCRF v1.10

I7a	Imaginable health state points score *Best imaginable=100 / worst imaginable=0*		☐ Not done ☐ Not known
I7b	Who answered the question?	☐ Participant ☐ Carer	☐ Not applicable ☐ Not known

1. Collect VAS score

You do not need to backfill data for existing participants, please collect for participants recruited after implementation of SA_06_24.

Section J: Clinical frailty scale

Pre-morbid clinical frailty scale, judged on their ability approx. 2 weeks prior to admission

Scoring guide: https://stroke.nottingham.ac.uk/tich-3/links/CFS

J1	Clinical frailty scale	☐ 1 - Very fit ☐ 2 - Well ☐ 3 - Managing well ☐ 4 - Vulnerable ☐ 5 - Mildly frail ☐ 6 - Moderately frail ☐ 7 - Severely frail ☐ 8 - Very severely frail ☐ 9 - Terminally ill	☐ Not done ☐ Not known

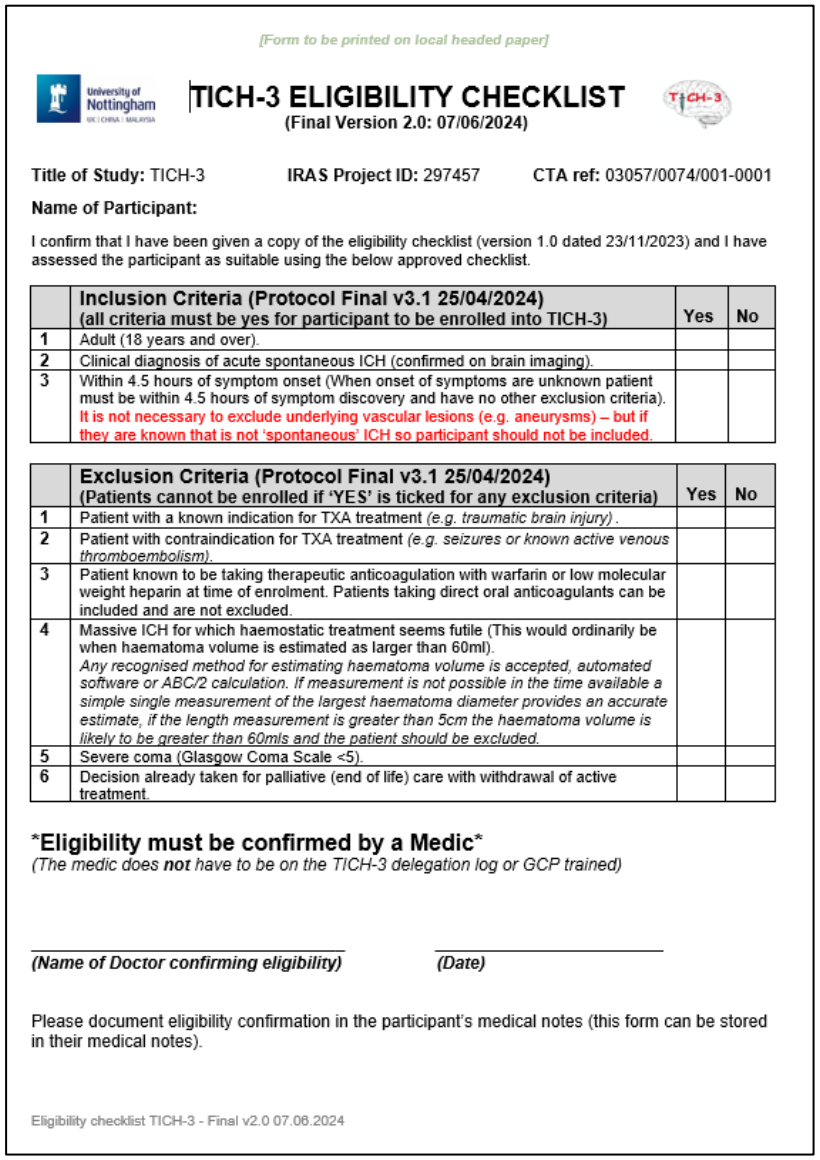
2. Collect pre-stroke baseline CFS

You do not need to backfill data for existing participants, please collect for participants recruited after implementation of SA_06_24.

A2	Please give the name of the investigator taking initial consent for enrolment in the trial	*Where a medic (non-investigator) took consent out of hours, please write 'Consent by eligibility check list'.*	☐ Not known

3. If eligibility and enrolment form used please state this on question A2

Updated document – eligibility checklist



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University of Nottingham

TICH-3 ELIGIBILITY CHECKLIST
(Final Version 2.0: 07/06/2024)

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

Name of Participant:

I confirm that I have been given a copy of the eligibility checklist (version 1.0 dated 23/11/2023) and I have assessed the participant as suitable using the below approved checklist.

	Inclusion Criteria (Protocol Final v3.1 25/04/2024) (all criteria must be yes for participant to be enrolled into TICH-3)	Yes	No
1	Adult (18 years and over).		
2	Clinical diagnosis of acute spontaneous ICH (confirmed on brain imaging).		
3	Within 4.5 hours of symptom onset (When onset of symptoms are 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 (Protocol Final v3.1 25/04/2024) (Patients cannot be enrolled if 'YES' is ticked for any exclusion criteria)	Yes	No
1	Patient with a known indication for TXA treatment *(e.g. traumatic brain injury)*.		
2	Patient with contraindication for TXA treatment *(e.g. seizures or known active venous thromboembolism)*.		
3	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 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). *Any recognised method for estimating haematoma volume is accepted, automated software or ABC/2 calculation. If measurement is not possible in the time available a simple single measurement of the largest haematoma diameter provides an accurate estimate, if the length measurement is greater than 5cm the haematoma volume is likely to be greater than 60mls and the patient should be excluded.*		
5	Severe coma (Glasgow Coma Scale <5).		
6	Decision already taken for palliative (end of life) care with withdrawal of active treatment.		

Eligibility must be confirmed by a Medic
*(The medic does **not** have to be on the TICH-3 delegation log or GCP trained)*

_____ _____
(Name of Doctor confirming eligibility) ***(Date)***

Please document eligibility confirmation in the participant's medical notes (this form can be stored in their medical notes).

Eligibility checklist TICH-3 - Final v2.0 07.06.2024

Updated in line with recent protocol amendment SA06 and MA24.

This is a different document to the eligibility checklist and enrolment form, this is to just simply document eligibility alone, if you wish too. Please use the other form if a clinical non-delegated team member is assessing eligibility and documenting enrolment into the TICH-3 trial when no-one from the research team is available.

Eligibility can be confirmed by a medic that is not on the TICH-3 delegation log. An appropriate research team member on the delegation will then take oral enrolment consent, this can be completed remotely.

There is an eligibility checklist on the TICH-3 documents page that can be used to document participants eligibility confirmation whether this was completed remotely or on site.

This is an optional document that is not required to be completed but is available if you wish to use this.

All processes off eligibility assessment and consent must be documented in the participants medical notes.

Safety Events, SARS and SUSARS

Please remember that investigators have a legal responsibility to report applicable SAEs to the chief investigator within 24 hours of being made aware of the event.

TXA has an established safety record – we only collect data on focused **safety outcomes** occurring within the **first 7 days or events suspected to be related to the IMP (SAR or SUSAR):**

Safety outcomes: **If a safety outcome (e.g. seizure) occurs during infusion, the infusion must be stopped immediately**

1. Venous occlusive events: VTE (Pulmonary embolism, Deep vein thrombosis)
2. Ischaemic events (arterial thrombosis at any site, ischaemic stroke, transient ischaemic attack peripheral artery embolism, myocardial infarction, acute coronary syndrome)
3. Seizures
4. Fatal events up to discharge from hospital

Serious adverse reactions (SAR) or Suspected Unexpected Serious Adverse Reactions (SUSAR):

- All events suspected to be related to the IMP will be assessed for seriousness, expectedness and causality by local investigator. Section 4.8 of the SmPC, date of last revision 02 February 2021, will act as the **Reference Safety Information:** Tranexamic Acid https://Tranexamic Acid_SmPC_20210202_REVISION.pdf

Serious Adverse Events (SAEs) that are not safety outcomes, SARS or SUSARS should not be reported

E.g. Neurological deterioration, haematoma expansion, cerebral oedema that is NOT thought to be related to the IMP, and does not result in death does not need to be reported as an SAE

Data corrections

Please check if you have any outstanding data corrections to complete by reviewing your participant list on the TICH-3 website.

You will see an alert for any outstanding data queries when you click on participant list, click on this and it will show open queries for actioning.

There is one active data query

Please click on the CRF where the data query is located i.e. in this example Day 7. You can also they can also click on the issue ID (glint+seesaw) to go directly to the specific query/questions

Open queries for C001
NOTTINGHAM, Nottingham DEMO Hospital, UK

Participant ID	CRF	Question IDs/query details	Date/time/ data query ID	Assigned to
C001-0002-ONK	Day 7	A2c 'Test' isn't a valid reason.	6 Oct 2022 12:50 glint+seesaw	Haywood, Lee centre 1

Found one matching data query

Please ensure you complete a data correction on any 'ongoing' SAEs once they become resolved.

Click here for data correction guidance on the TICH-3 documents page

Co-enrolment with TICH-3

Co-enrolment is permitted, and sponsor approved for the following University of Nottingham sponsored trials (contract with site not required)

- MAPS-2 (IC now up-to 24 hours to enrol)
- PhEAST (IC now 2 – 31 days)

Co-enrolment has been agreed with the following non-University of Nottingham sponsored CTIMPs (contract with site REQUIRED before co-enrolment is permitted)

- TRIDENT
- ENRICH-AF (MASTER CONTRACT NOW AGREED)

If you are taking part in either trial above, please let us know so your site (PI and R&I) can document they agree to co-enrolment at your site.

NEW CO-ENROLMENT AGREEMENT IMPLEMENTED FOR NEW TRIALS, does not need localising at each site, the master agreement signed by the 2 trials CIs – please get in touch to discuss any co-enrolment.

- **Currently considering EASE**

Please let us know if there are any other trials you may wish to co-enrol with so that we can begin the contracts/agreement process.

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

There is a co-enrolment log on the TICH-3 documents page https://stroke.nottingham.ac.uk/sif/docs/?sid=TICH3

Protocol compliance

Overall v good thank you!

- Check the CT scan ? <60mls ? lesions
- Person taking consent must have training - or use the eligibility form
- Give all 4 vials of IMP as per protocol
- Only give IMP to participants in the trial

Protocol violation counts – accepted / all unevaluated

Baseline characteristics

- \- Known indication for TXA treatment at time of randomisation
- \- Patient with contraindication for TXA treatment
- 4 × Massive ICH for which haemostatic treatment seemed futile (usually when HV>60 mls)
- \- Severe coma (Glasgow Coma Scale less than 5) at time of randomisation
- \- Decision already taken for palliative care at time of randomisation
- 2 × Baseline scan not eligible (e.g. no ICH, underlying lesion/tumour)

Consent

- \- Failure to obtain written consent when possible
- 2 × Individual taking consent not authorised to take consent on delegation log

Practice during the trial

- \- Failure to report SARs/SUSARs/safety events where appropriate
- 1 × Randomised more than 4.5 hours after onset
- 4 × Participant received no IMP or partial dose(s) of IMP
- 3 × Participant did not receive randomised treatment as per protocol

Management of IMP (non-participant records)

- \- TICH-3 treatment pack(s) lost
- 1 × TICH-3 treatment pack used on patient not in trial

Miscellaneous

- 1 × Any other major violation of the trial protocol

Matched 18 protocol violations

ICH update from ESOC

INTERACT – 4

- **Pre-hospital BP lowering improved outcome after ICH**

OR 0.75; 95% CI, 0.60 to 0.92

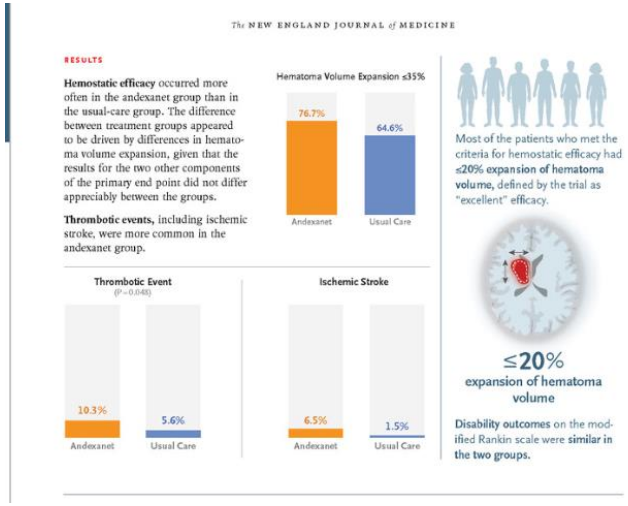
https://www.nejm.org/doi/full/10.1056/NEJMoa2314741

SWITCH decompression surgery

Improved outcome in per-protocol analysis – volume 55mls

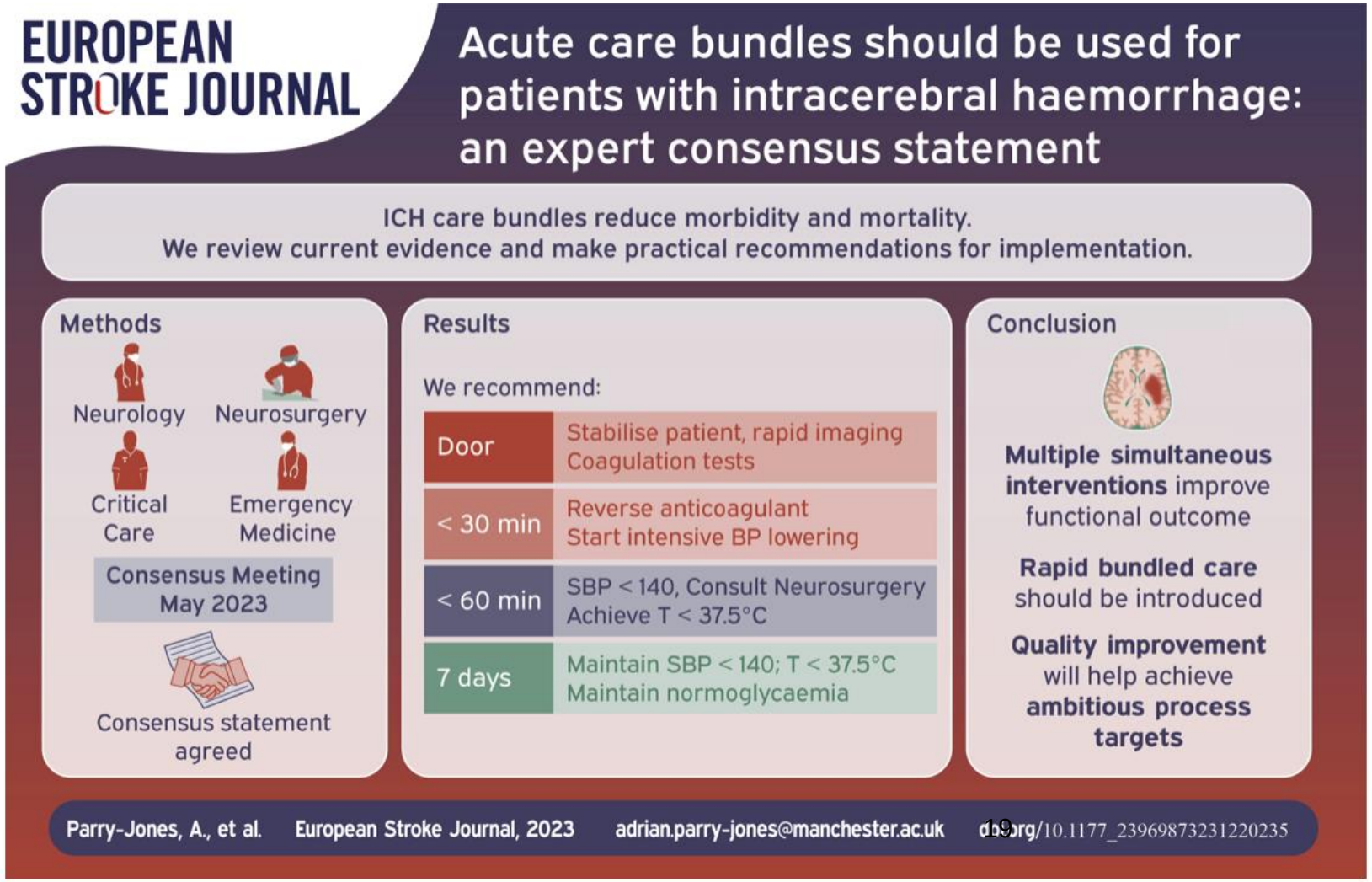
https://doi.org/10.1016/S0140-6736(24)00702-5

Andexanet for FXa Inhibt (DOAC) ICH



N Engl J Med 2024;390:1745-1755
DOI: 10.1056/NEJMoa2313040

Bundles of care – ESO consensus statement



https://doi.org/10.1177/23969873231220235

Upcoming events

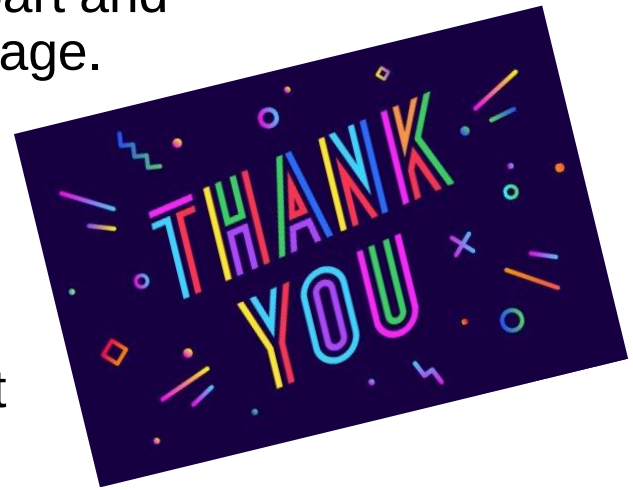
- International Clinical Trials Methodology Conference (ICTMC), Edinburgh, September 2024

- UK Stroke Forum (UKSF) December 2024, Liverpool

Acknowledgements

TICH-3 would not be possible without:

All our participants and their families – we thank them for agreeing to take part and help us try to find better treatments for stroke due to intracerebral haemorrhage.



Thank you also to:

- TICH-3 Investigators
- TICH-3 staff Nottingham Stroke Trials Unit, Nottingham Clinical Trials Unit
- TICH-3 co-applicants
- Collaborators including Andrew Willis
- Nottingham Stroke Research Partnership Group - PPIE
- TICH-3 trial steering committee, data monitoring committee
- Funders – NIHR HTA

The Centre for Ethnic Health Research
national centre for tackling health inequalities

TICH-3 is funded by National Institute of Health and Care Research (Health Technology Assessment 19/59) NIHR129917

FUNDED BY NIHR | National Institute for Health and Care Research

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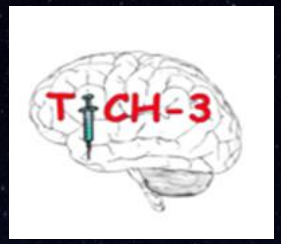

Any questions?

Question & Answers (1)

- Q: Can the non-delegated/GCP train physician that takes consent this way still be permitted to act as independent physician for a different recruit?
- A: Yes, for a different recruit
- Q: I am medic in A&E not on the delegation log to take consent – can I now take consent?
- A: Yes, if no-one from the research team withy code J delegated is available. This is then documented using the eligibility checklist and enrolment form.

Question & Answers (2)

- Q: I am delegated on the TICH-3 online delegation log with code J (taking enrolment consent for CTIMPs) If I am not on the Ward but receive a call, can I enrol the participant?
- A: Yes, remote consent is permitted as it is oral consent in the first instance for enrolment, you don't have to be physically there

- Q: Regarding "symptom discovery", what if the patient is found on the floor?
- A: It is within 4.5 of being found

- Q: When do we take the VAS score? Is it prior to Stroke or at the time of seeing them?
- A: Yes, premorbid