

TICH-3 NEWSLETTER

ISRCTN: 97695350 May 2024, Issue 11



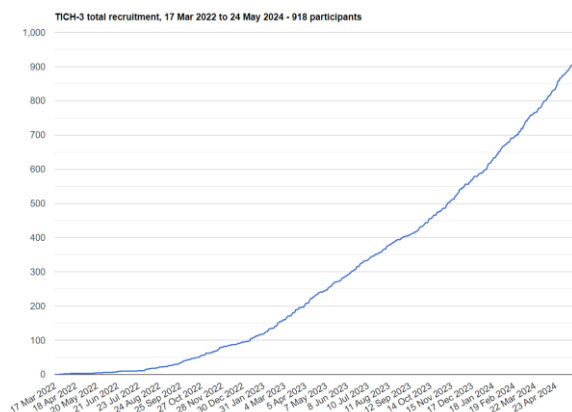
TICH-3@nottingham.ac.uk



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

Useful documents: <https://stroke.nottingham.ac.uk/tich-3/docs/>

RECRUITMENT UPDATE Combined total **926** International total **349**



577 UK Participants!

TICH-3 has recruited a further 76 UK participants since the last newsletter, 20/03/2024 thank you so much for your continued support!

PROTOCOL AMENDMENT SA06 & MA24

We implemented a protocol amendment on 09/05/2024. The protocol you must now adhere to is **Protocol Final v3.1 25/04/2024**.

The impact on sites is to

- Collect pre- stroke EQOL-VAS and pre-stroke clinical frailty score at baseline
- Permit consent by clinician not on the delegation log. This consent method is to **ONLY** be used when a delegated TICH-3 investigator is not available to take enrolment consent. The medic will read the synopsis and then document eligibility assessment and enrolment using the eligibility checklist and enrolment form.

Download and localise the form for you site from the TICH-3 documents page

[Click here for link to the TICH-3 documents page](#)

TRIAL DOCUMENTS UPDATES

The training documents below have been amended in line with the recent protocol amendment.

Training slides updated (no major changes to process) – audit list of changes available at the end of each training slide set

- Enrolling Investigator Training v3.0 23.04.2024
- Pharmacy Training v3.0 23.04.2024
- Investigator Training v4.0 23.04.2024
- Ward Training Final v2.0 23.04.2024

We recommend reading these every few months as a refresher to the trial.

New team members can read the appropriate slides for their role

[Click here for link to TICH-3 documents page](#)

Please then complete self-referral form to be added to the online delegation log

[Click here for link to TICH-3 self-referral form](#)

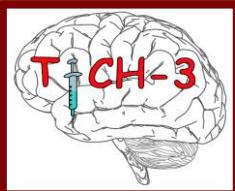
eCRFs update The eCRFs data are intended to be inputted straight from the medical record electronically.

Changes to the Enrolment Form v1.10

- Added drop down A2 'Consent by eligibility check list'.
- Added 17a and 17b VAS scale
- Added section J Clinical frailty scale and included not applicable option for non-UK sites

Congratulations on the recent TICH-3 recruitment!

- 5 Royal London Hospital
- 4 Addenbrooke's Hospital
- 4 Southampton General
- 4 UCLH
- 3 Aberdeen Royal Infirm
- 3 Charing Cross
- 3 Luton and Dunstable
- 3 QE Birmingham
- 3 Royal Infirmary of Edinburgh
- 3 Salford Royal
- 3 St George's
- 2 Craigavon Area Hospital
- 2 James Cook Uni Hospital
- 2 Leeds General Infirmary
- 2 New Cross Hospital
- 2 Queen's Medical Centre
- 2 Royal Stoke Uni Hospital
- 2 Southmead Hospital
- 2 Yeovil District Hospital
- 1 Aintree Uni Hospital
- 1 Darent Valley Hospital
- 1 Kent and Canterbury
- 1 King's College Hospital
- 1 King's Mill Hospital
- 1 Lincoln County Hospital
- 1 Milton Keynes Hospital
- 1 Northumbria Specialist Emergency Care Hospital
- 1 Northwick Park Hospital
- 1 Peterborough City Hosp
- 1 Royal Cornwall Hospital
- 1 Royal Derby Hospital
- 1 Royal Devon and Exeter
- 1 Royal Preston Hospital
- 1 Royal United Hospital
- 1 South West Acute
- 1 Southend Uni Hospital
- 1 University Hospital Monklands
- 1 University Hospital of North Durham
- 1 University Hospital of North Tees
- 1 Victoria Hospital, Fife



SAE REPORTING

When reporting safety events through the SAE form, please ensure you have discussed with a medic at the local site as we have had a few events reported that assessed the relationship to the IMP as possible when it was improbable, which also changes the event classification from SAR to SAE.

A10a Relationship to study drug

Not related
 Improbable
 Possible
 Probable
 Definite

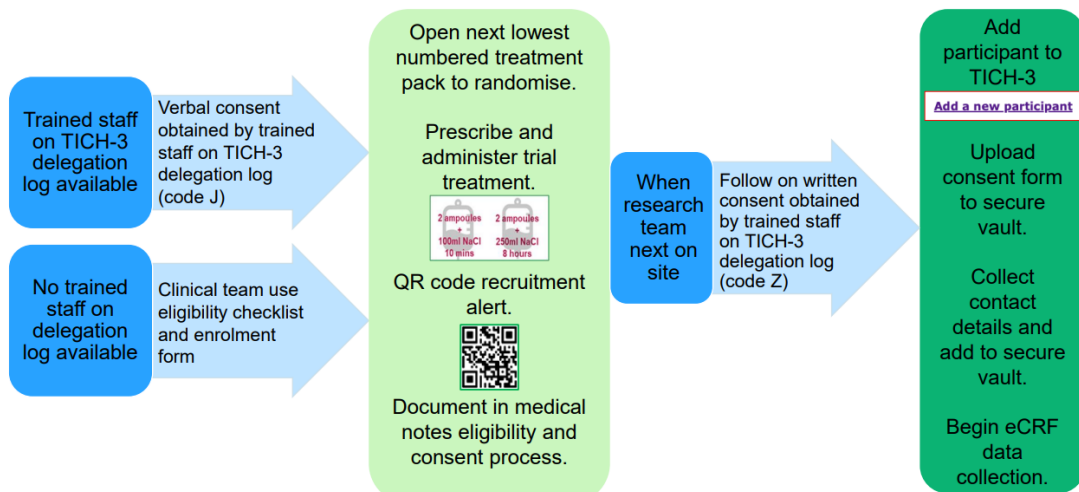
A10b Please classify the event

SAR
 SAE
 SUSAR

Please assess if expected according to SmPC.
 Expectedness should only be assessed in events that are thought to be possibly/probably/definitely related to the IMP.

Welcome to the TICH-3 trial!
 • West Suffolk Hospital

CONSENT PROCESS FLOWCHART



UNDER PRESSURE – TO LOWER BP: INTERACT-4

Hyperacute blood pressure lowering treatment to a target of <140mmHg improved functional outcome - given the interaction between BP and TXA in TICH-2 we suspect a likely synergistic relationship with BP lowering and TXA
<https://www.nejm.org/doi/10.1056/NEJMoa2314741>

KEEPING IN TOUCH AND UPDATE MEETINGS

We would like to invite you all to join the TICH-3 trial team where we will discuss topics of interest for the trial:

Thursday 13th June 12.30 – 1.30pm [Join the meeting now](#)

Invitations will also have been sent to your email address so look out for these!

If you have any points you would like to discuss, please email the team and we will add them to the meeting.

You can find us on Twitter: [@tich3trial](#) and [@UoN_STU](#)

Please feel free to tweet us or tag us in your Stroke related tweets



Conferences coming up

- International Clinical Trials Methodology Conference (ICTMC) Edinburgh, Sept 2024
- UK Stroke Forum (UKSF) Liverpool, 3 – 5th December 2024

TICH-3 EMERGENCY PHONE NUMBERS

For urgent medical enquiries and for randomisation problems
 +44 (0)7725 580 092
 +44 (0)7736 843 592
 +44 (0)7798 670 726
 +44 (0)7810 540 604