

ISRCTN: 97695350 December 2023, Issue 9

177



TICH-3@nottingham.ac.uk http://tich-3.ac.uk/ Useful documents: https://stroke.nottingham.ac.uk/tich-3/docs/

RECRUITMENT UPDATE Current totals

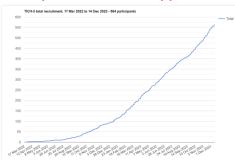
400

International





TICH-3 has recruited a further 46 UK participants since the last newsletter, 27/10/2023 thank you so much for your continued support!



PILOT PROGRESSION REVIEW UPDATE

HTA are pleased with the current achievements of the TICH-3 trial given UK wide capacity issues and we are delighted to say we can continue with the trial! The TICH-3 trial would not be possible without the support of our investigators,

thank you for helping us reach 61 active sites in the UK and 400 participants!

There will be another data review in September 2024 with targets

- 80 UK sites open and recruiting
- 1100 participants recruited

We are still recruiting hyperacute stroke units and investigators in the UK, PLEASE JOIN US!

OUT OF HOURS RECRUITMENT

The process is very simple for out of hours recruitment

- **Confirm eligibility** medic confirming eligibility does not need to be on the TICH-3 delegation log or GCP trained.
- 2. **Take initial oral enrolment consent -** consent process just needs to be documented in the medical record. Person taking consent must have code J delegated on the online TICH-3 delegation log.
- 3. **Prescribing and administration of the IMP** – completed by anyone trained to do so, do no need to be GCP trained or on delegation log.
- 4. **Complete QR code recruitment alert** – found within each treatment pack, can be completed by anyone, no logins required.
- 5. When the research team is next on site – follow on written consent is obtained and data collection for eCRFS.





TRIAL DOCUMENTS UPDATES

These are not ethically approved documents and therefore there are not any approvals to coincide with this updates.

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

- Enrolling Investigator Training v2.2 11/12/2023
- Pharmacy Training v2.2 11/12/2023
- Investigator Training v3.3 11/12/2023
- SWAT Training (if enhanced consent site) v1.2 11/12/2023

New team members can read the appropriate slides for their role https://stroke.nottingham.ac.uk/tich-3/docs then complete self-referral to be added to the online delegation log http://tich-3.ac.uk/?ZSelfRef

Co-enrolment log update

PhEAST inclusion criteria is now 2 – 31 days after the index stroke. There is no washout period required for TICH-3 co-enrolment with PhEAST.

eCRFs update

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

Enrolment v1.7

- Added E2b: Intraventricular haemorrhage (IVH) present on scan? Day 7 follow-up v1.6
- Added A3a: Was tranexamic acid given open-label as part of clinical care?
- Added A3b: If yes, please provide explanation.

ASSISTANCE OVER CHRISTMAS PERIOD

University of Nottingham is closed Friday 22nd December reopening Tuesday 2nd January 2024. We will continue to provide support for the trial over this period.

Any non-urgent queries please email TICH-3@nottingham.ac.uk and we will get back to you as soon as we can.

For urgent SAE/protocol violation queries call 0115 8231782

For urgent eligibility queries/unblinding please call the emergency phone numbers

+44 (0)7725 580 092 +44 (0)7736 843 592

+44 (0)7798 670 726 +44 (0)7810 540 604

KEEPING IN TOUCH AND INVESTIGATOR 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 25th January 2024 12.30 – 1.30pm Click here to join the meeting

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.

invited! 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 Stroke Conference (ISC) 2024