****

**ELIGIBILTY CHECKLIST AND ENROLMENT FORM**

**(Final Version 1.0: 28/02/2024)**

**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 1.0 dated 28/02/2024*) 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 v3.0 28.02.2024) |
| 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

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 +10mls).
* 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- treatment to be given within 4.5 hours of stroke onset and trial team notified
 |
| **I confirm the patient, relative or independent doctor gives permission to proceed with treatment (please circle):** Yes / NoName 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**

**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 for the participant to proceed with the trial treatment. Full written consent will be taken later.

**If the patient is not eligible, or you do not feel able to decide, the patient must not be given trial treatment.**

**Background of TICH-3**

TICH-3 is a randomised placebo-controlled trial to assess whether tranexamic acid reduces the risk of death and/or improves disability 6 months after stroke due to intracerebral haemorrhage (ICH). Because ICH is an emergency and the potential benefits of tranexamic acid (TXA) 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. Treatment needs to be started within 4.5 hours of onset of stroke due ICH.

**Risks of tranexamic acid**

Tranexamic acid has an established safety profile, adverse effects are generally mild, (diarrhoea, low blood pressure and dizziness), but it can cause deep vein thrombosis and pulmonary embolism. However, in previous studies in stroke patients, and in emergency bleeding due to trauma, involving many thousands of patients, tranexamic acid at the dose used here was safe and did not increase venous thromboembolism. Tranexamic acid is contra-indicated in patients with seizures as it lowers the seizure threshold.

**Consent**

ICH is an emergency and seeking full written consent is not possible – however it is important to check with the patient or their relative if they wish to proceed with the study treatment. This approach is in accordance with emergency consent procedures and was designed with stroke survivors.

Please explain that the study is being done to see whether using the drug tranexamic acid will help patients with ICH by reducing the amount of bleeding into the brain, therefore preventing further brain damage. If enrolled in the study the patient will be given an infusion into a vein of either tranexamic acid or a dummy medicine (a liquid which does not contain tranexamic acid called a placebo). Tranexamic acid has been shown to improve outcome in patients with other types of severe injury and bleeding and that TXA appeared to be safe. However, whilst we hope that tranexamic acid will improve recovery after ICH, at present we cannot be sure about this.

**Please explain to the potential participant (or their relatives if patient lacks capacity) that entry into the trial is entirely voluntary and that their treatment and care will not be affected by their decision.** The participant is free to withdraw at any time and without giving a reason, without it affecting their care. This would not affect their legal rights.

**Further information:**

A brief information sheet will be provided if practicable and time allows, and detailed written information will be provided as soon as possible afterwards prior to full written consent. **If the patient or their relative objects to the inclusion of the patient in the trial, their views will be respected, and the patient must not be enrolled or given trial treatment.**

**Treatment:**

If the participant (or relative) agrees you will advise the clinical team to go ahead with prescription and administration of treatment. Each treatment pack contains either TXA or placebo and a prescribing and administration guide. The study drug will be administered by slow IV by qualified nursing staff.

**Safety:**

If you are concerned about an adverse reaction to the study treatment during administration (immediately stop the infusion) or after administration, treat the patient in accordance with clinical guidelines, please then report this to the research team and call the emergency helpline number.

There is an emergency helpline for TICH-3 available 24 hours a day, including emergency unblinding:

07725 580 092     07736 843 592 07798 670 726     07810 540 604

**Further guidance documents:** FAQs and guidance documents