Fw: TICH-3 Newsflash - March 2021

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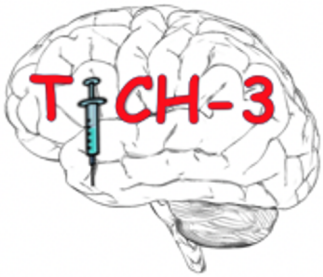
TICH-3 NEWSFLASH | MARCH 2021



Tranexamic acid for Hyperacute Primary Intracerebral Haemorrhage (TICH-3)

NEWSFLASH

UPDATE: We are delighted to announce that TICH-3 has now been awarded funding by the NIHR HTA.

EXPRESSION OF INTEREST

If you are still interested in taking part in the TICH-3 study, please click the link below which will take you to a form to fill in required details:

https://forms.office.com/r/C5Tngj2c9r

Please ensure to complete it only once per site - thank you!

DEADLINE: 12th April 2021

TIMELINE - IMPORTANT DATES

GRANT START: 01 May 2021

APPROVALS & SETUP: between May 20201 & August 2021

RECRUITMENT START: from start of late 2021 (Q1/Q2)

TRIAL SUMMARY

BACKGROUND: ICH can be devastating with high early mortality and disability in survivors, with outcome related to volume of haematoma and haematoma growth. Tranexamic acid (TXA) reduces mortality in other bleeding conditions when given early and reduced haematoma growth in the previous study, TICH-2.

AIM: To assess the clinical effectiveness of TXA after ICH and determine whether TXA should be used in clinical practice; primarily on early death (≤7days), but also on dependency 6 months after ICH.

SETTING: Estimated 100 UK sites & 65 international sites will be involved in TICH-3. The inclusion of sites outside the UK will enable the recruitment of 5500 participants.

EXCLUSION/INCLUSION CRITERIA: The exclusion & inclusion criteria are

similar to TICH-2, with the exception that we will only enrol patients up to 4.5 hours and exclude those with established large haematomas:

INCLUSION CRITERIA:

- Over 18 years old
- Has a ICH, confirmed by brain imaging, within 4.5 hours of onset of ICH

EXCLUSION CRITERIA:

- Massive ICH for which treatment seems futile (estimated haematoma vol>60mls), Glasgow Coma Scale <5, palliative care

INTERVENTION: Intravenous TXA (2g) given as 1g bolus in 100 ml normal saline 0.9% infusion over 10 min and 1g infusion in 250 ml normal saline 0.9% over 8 hours. Placebo (normal saline 0.9%) administered by an identical regimen. Randomisation will be to TXA vs. placebo in a 1:1 ratio.

RECRUITMENT TIMELINE: UK sites will be recruiting participants for just over 5 years.

CONSENT: We are seeking Ethical approval for rapid emergency consent process, with verbal permission obtained to administer the IMP, followed later by a written consent.

FOLLOW-UP: There will be local follow-up at day 7 (or death/discharge from hospital if sooner) & centrally at 6 months (by post or telephone by the coordinating centre).

For any queries, email:

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SUPPORTED BY NIHR | National Institute for Health Research

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