

RESULTS FROM THE TRANEXAMIC ACID FOR PRIMARY INTRACEREBRAL HAEMORRHAGE-2 (TICH-2) TRIAL

Nikola Sprigg¹, Katie Flaherty¹, Zhe Kang Law¹, Jason P Appleton¹, Polly Scutt¹, Kailash Krishnan¹, and Philip M Bath¹; on behalf of the TICH-2 investigators.

¹Stroke Trials Unit, University of Nottingham, Nottingham NG5 1PB UK

Background

Haematoma expansion leads to worse outcome in intracerebral haemorrhage (ICH). Tranexamic acid (TXA) is a promising haemostatic agent to prevent haematoma expansion and improve outcome after ICH.

Methods

TICH-2 is a multicentre prospective double blind randomised controlled trial, which recruited patients presenting within 8 hours of primary ICH to receive intravenous TXA or placebo. Primary outcome is modified Rankin Scale at day 90 and will be analysed using ordinal logistic regression, adjusted for minimisation criteria. Secondary outcomes will be analysed using adjusted binary logistic regression and multiple linear regression; these include haematoma expansion at 24 hours, day 7 National Institute of Health Stroke Scale (NIHSS), day 90 Barthel Index, quality of life, cognition and mood.

Results

A total of 2325 patients were recruited between 14th March 2013 and 30th September 2017, from 12 countries: United Kingdom (n= 1910), Italy, Georgia, Switzerland, Malaysia, Hungary, Poland, Ireland, Turkey, Sweden, Denmark and Spain. Randomisation characteristics included: age 68.9 (13.8) years; male 1301 (56.0%); time from onset to randomisation 3.6 hours [2.6, 5.0]; NIHSS 13 (7.5); Glasgow coma scale 13.4 (2.1); systolic blood pressure 172.6 (27.2) mmHg; intraventricular haemorrhage 745 (32.0%) and prior antiplatelet use 610 (26.2%).

Conclusion

TICH-2 is the largest trial of TXA in spontaneous ICH and recruited over its original target of 2000 patients. The results will be available in May 2018 and will inform whether TXA should be recommended for the treatment of acute spontaneous ICH.