Rationale: To assess in a pragmatic phase III prospective double blind randomised placebo-controlled trial whether tranexamic acid is safe and reduces death or dependency after spontaneous intracerebral haemorrhage (SICH). The results will determine whether tranexamic acid should be used to treat ICH.

Design: Patients will be randomised (1:1) to receive either tranexamic acid or placebo (0.9 % saline) within 8 hours of acute SICH. Randomisation will be computerised and minimised on key prognostics age; sex; time since onset; systolic blood pressure; stroke severity (NIHSS); presence of intraventricular haemorrhage and known history of antiplatelet treatment. Patients, investigators and outcome assessors will be blind to treatment allocation. The primary outcome is death or dependency (modified Rankin Scale) and telephone follow-up is at day 90.

Trial status: The start-up phase of the trial commenced on 1st March 2013, the main phase commenced 1st April 2014. The recruitment target was 300 participants in the start-up phase and 2,000 in the main phase. As of 30th May 2017, 2191 patients have been recruited from 123 centres (UK, Georgia, Italy, Malaysia, Switzerland, Republic of Ireland, Turkey, Sweden, Denmark, Hungary, Spain and Poland). The objective was to have 80 UK centres and 40 international centres.

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