Tranexamic acid for acute intracerebral hemorrhage growth based on imaging assessment (TRAIGE)

Objective: To assess efficacy and safety of tranexamic acid (TXA) in prevention of hematoma growth in high-risk spontaneous ICH patients predicted by CT signs

Design: Multicenter, double-blind, placebo-controlled trial with randomized treatment group assignments

Randomization: Random assignment in a 1:1 ratio to TXA or placebo

Inclusion: 18-79 years old spontaneous ICH within 6 hours, spot sign (+), blend sign (+) or black hole sign (+)

Intervention:

- TXA: 1 g in 100 ml 0.9% NaCl infusion over 10 min + 1 g in 250 ml 0.9% NaCl infusion over 8 h
- Placebo: same administration regimen

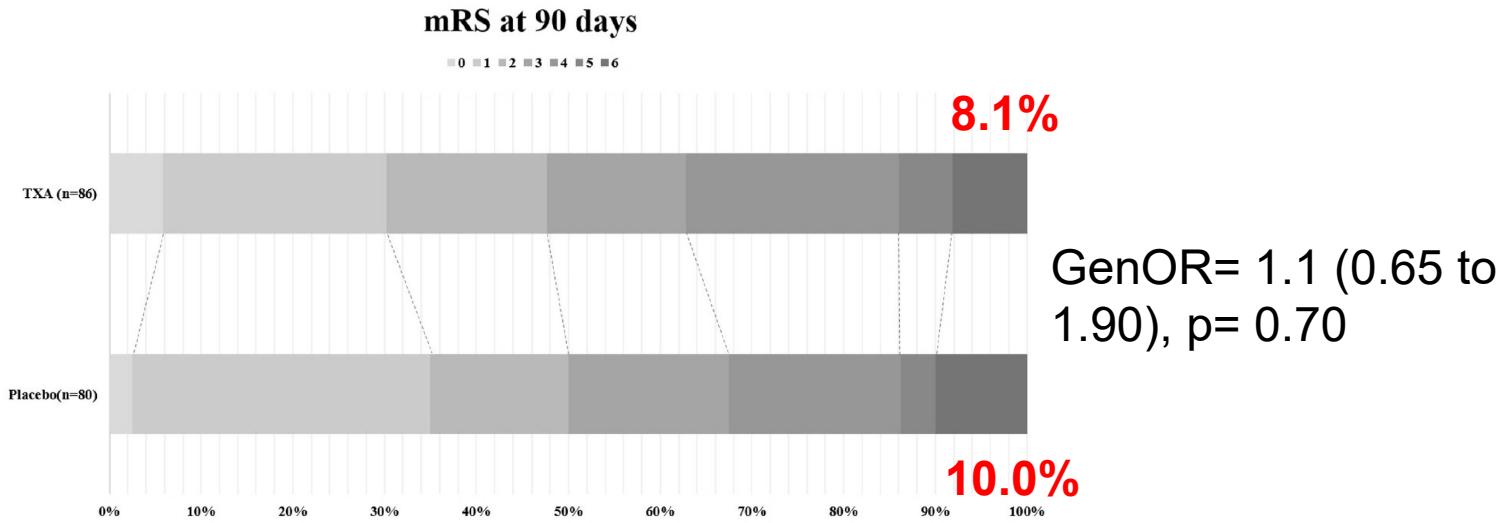
Primary outcome: Hematoma expansion at 24 h (absolute increase> 6 ml or relative growth> 33%)

Demographics, time metrics and treatment

	TXA (n=89)	Placebo (n=82)
Age (years)	56.7±12.2	55.0±10.8
Male	124 (72.5%)	63 (70.8%)
NIHSS	11 (7-15)	10 (6-15)
ICH volume (ml)	25.3±19.7	22.0±17.5
Spot sign	50 (56.2%)	44 (53.7%)
Black Hole sign	25 (28.1%)	22 (26.8%)
Blend sign	56 (62.9%)	51 (62.2%)
Onset to treatment (min)	290 (205-369)	285 (180-378)
SBP_{max} during treatment (mmHg)	99.5±13.8	101.5±18.0

Primary outcome, secondary outcomes and safety outcome

	TXA (n=89)	Placebo (n=82)	Risk Ratio (95% CI)	P value
Hematoma expansion at 24 h	36 (40.4%)	34 (41.5%)	0.96 (0.52 to 1.77)	0.89
24 h ICH growth volume	6.6±16.5	7.6±15.6		0.70
mRS 4-6 at 90 days	32 (37.2%)	26 (32.5%)	1.23 (0.65 to 2.33)	0.53
90-day mortality	7 (8.1%)	8 (10.0%)	0.82 (0.28 to 2.37)	0.71
Major thromboembolic events at 90 days	1 (1.2)	1 (1.3)		0.96



GenOR= 1.1 (0.65 to 1.90), p= 0.70