

ICTuS-2 Final Results



Purpose: This trial, a part of the Specialized Program of Translational Research in Acute Stroke (SPOTRIAS), compared hypothermia + thrombolysis vs. thrombolysis alone in acute ischemic stroke treatment.

Trial Design: A phase 2/3 trial. Randomized, single-blinded, parallel, efficacy study. IV t-PA and normothermia was compared to IV t-PA and hypothermia. N=120 (6.4% of the planned number).

Primary Endpoint: favorable outcome at 90 days after treatment - Modified Rankin Scale score of 0 or 1

Trial Results	Hypothermia	Normothermia	ITT Odds Ratio (OR)	Per Protocol OR
ITT Primary Outcome	33%	38%	1.37	0.89

Conclusions: This was a small patient sample. The outcomes were not statistically significant. Serious adverse events were similar for pneumonia and mortality.