

A EUROPEAN, MULTICENTRE, PHASE III, CLINICAL TRIAL OF HYPOTHERMIA FOR ACUTE ISCHAEMIC STROKE: EuroHYP-1

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Background: Cooling is a promising neuroprotective intervention in experimental ischaemic stroke; cooling to 35°C reduced infarct size by about one third. Cooling awake ischaemic stroke patients to 35°C has been shown feasible and safe, but whether this is safe and effective has not been tested in a large clinical trial.²

Aims: To determine whether systemic cooling to target temperature of 34 to 35°C, started within 6 hours of symptom onset and maintained for 12 hours, improves functional outcome at 3 months in patients with acute ischaemic stroke.

Methods: Open, randomised, phase III, multicentre, international clinical trial with masked outcome assessment testing the safety and efficacy of therapeutic cooling in 800 awake adult patients with acute ischaemic stroke. Cooling will be initiated within 6 hours of symptom onset with an intravenous infusion of 20 ml/kg cooled normal saline (4°C) over 30 to 60 minutes, followed by either surface or endovascular cooling to 34 to 35°C, maintained for 12 hours. Shivering and discomfort will be prevented and treated with anti-shivering drugs. All patients will receive best medical treatment, including alteplase, if indicated. The primary outcome is centrally adjudicated modified Rankin Scale at 90 days (shift analysis). A trial with 400 patients per arm has 80% power to detect a 7% absolute improvement in the mRS at the 5% significance level. As of 23rd October 2017, 87 patients have been recruited across 21 sites in 7 countries.

Conclusion: EuroHYP-1 is ongoing, funded by the European Commission 7th Framework Programme (FP7/2007-2013-278709).