

TENSION

Efficacy and safety of thrombectomy in stroke with extended lesion and extended time window: a randomized, controlled trial

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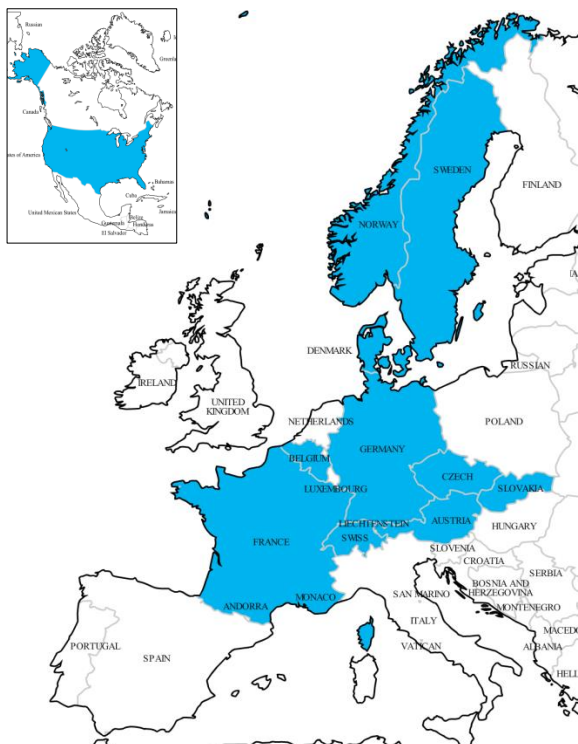
Total Budget



5.99 M€

Hospices Civils de Lyon
Budget

237 654 €



Patients with severe ischemic stroke have a lower risk of injury if they are treated quickly. TENSION, a European study, aims to demonstrate the effectiveness of an innovative treatment for patients who are treated later.

TENSION strives at providing innovative treatment to patients with severe stroke to reduce the individual and societal burden of death and dependency from stroke. To this end, TENSION is a randomized, controlled, prospective, open label, blinded endpoint (PROBE) trial of thrombectomy in stroke patients with extended ischemic stroke lesions and in patients presenting in a late time window, who are currently excluded from available effective treatment approaches. The trial will enrol up to 665 subjects in eight European countries. The primary endpoint is functional outcome at 90 days post-stroke measured by the Modified Rankin Scale. The primary effectiveness endpoint analysis is a chi-square test of the difference in linear trends in ordinal mRS outcomes between treatment groups (“mRS shift analysis”). Outcome evaluation will involve a comprehensive array of clinical and safety parameters, health and socio-economic outcomes including patient reported outcome measures (PROM) for evaluation according to the principles of value-based healthcare. Health economic evaluation with cost-effectiveness analysis will be performed and gender-effects on treatment and outcome will be studied. Trial organization will rely on a network of experienced partners with successful cooperation in previous EU-funded stroke trials. An image core lab will provide central judgement of all images acquired within the trial. Standards of image judgement and intervention will be defined and trial specific training will be provided to all investigators. TENSION addresses a major health problem and will provide evidence for more effective and safer therapeutic intervention for patients with severe stroke resulting in improved guideline development, better individual patient outcomes and beneficial effects for the society at large by reduction of stroke-related costs.

More information on: https://cordis.europa.eu/project/rcn/212667_en.html

Timeline of the project

