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

From 2018-01-01 to 2022-12-31, ongoing project

Objective

TENSION (efficacy and safety of ThrombEctomy IN Stroke with extended leSION and extended time window: a randomized, controlled trial) 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 patients presenting in a late time window, who are currently excluded from available effective treatment approaches. The trial will enroll up to 714 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.

Related information

Total cost: EUR 5 990 684,50
EU contribution: EUR 5 990 684,50
Coordinated in: Germany

Topic(s):
SC1-PM-10-2017 - Comparing the effectiveness of existing healthcare interventions in the adult population

Call for proposal:
H2020-SC1-2017-Two-Stage-RTD
See other projects for this call

Funding scheme:
RIA - Research and Innovation action
Coordinator

UNIVERSITAETS KLINIKUM HAMBURG-EPPENDORF
Martinistrasse 52
20251 HAMBURG
Germany
EU contribution: EUR 981 718,75

Activity type: Higher or Secondary Education Establishments
Contact the organisation

Participants

UNIVERSITAETS KLINIKUM HEIDELBERG
IM NEUENHEIMER FELD 672
69120 HEIDELBERG
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EU contribution: EUR 2 455 357

Activity type: Higher or Secondary Education Establishments
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MEDIZINISCHE UNIVERSITAT INNSBRUCK
CHRISTOPH PROBST PLATZ 1
6020 INNSBRUCK
Austria
EU contribution: EUR 142 125

Activity type: Higher or Secondary Education Establishments
Contact the organisation

FAKULTNI NEMOČNICE HRADEC KRALOVE
SOKOLSKA 581
500 05 HRADEC KRALOVE
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EU contribution: EUR 60 125

Activity type: Research Organisations
Contact the organisation

AARHUS UNIVERSITETSHOSPITAL
PALLE JUUL-JENSENS BOULEVARD 99
8200 AARHUS
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EU contribution: EUR 212 787,50

Activity type: Research Organisations
Contact the organisation
CENTRE HOSPITALIER UNIVERSITAIRE DE REIMS
45 RUE COGNACQ JAY
51092 REIMS CEDEX
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**Activity type:** Public bodies (excluding Research Organisations and Secondary or Higher Education Establishments)

Contact the organisation

OSLO UNIVERSITETSSYKEHUS HF
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**Activity type:** Higher or Secondary Education Establishments

Contact the organisation

STOCKHOLMS LANS LANDSTING
HANTVERKARGATAN 45
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**Activity type:** Public bodies (excluding Research Organisations and Secondary or Higher Education Establishments)

Contact the organisation

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814 99 BRATISLAVA
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**Activity type:** Higher or Secondary Education Establishments

Contact the organisation

HOSPICES CIVILS DE LYON
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**Activity type:** Public bodies (excluding Research Organisations and Secondary or Higher Education Establishments)

Contact the organisation
ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK
5 RUE WATT
75013 PARIS
France

EU contribution: EUR 285 182,50

Activity type: Research Organisations
Contact the organisation

EPPDATA GMBH
MEHLBEERWEG 10
22391 HAMBURG
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EU contribution: EUR 464 750

Activity type: Private for-profit entities (excluding Higher or Secondary Education Establishments)
Contact the organisation

EUROPEAN SOCIETY OF MINIMALLY INVASIVE NEUROLOGICAL THERAPY
SEEFELDSTRASSE 88
8008 ZURICH
Switzerland

EU contribution: EUR 92 100

Activity type: Other
Contact the organisation

STROKE ALLIANCE FOR EUROPE
RUE WASHINGTON 40
1050 BRUSSELS
Belgium

EU contribution: EUR 78 375

Activity type: Other
Contact the organisation

INTERNATIONAL CONSORTIUM FOR HEALTHOUTCOMES MEASUREMENT INC.
14 ARROW STREET SUITE 11
02215 CAMBRIDGE MA
United States

EU contribution: EUR 78 375

Activity type: Other
Contact the organisation

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