

Trial Description

Title

Impact of Anesthesia during endovascular treatment of acute ischemic stroke

Trial Acronym

STENOSIS

URL of the trial

[---]*

Brief Summary in Lay Language

In this study we will analyse the effect of anesthesia (general anesthesia or sedation) during endovascular therapy in acute ischemic stroke

Brief Summary in Scientific Language

Endovascular clot retrieval in acute ischemic stroke can be performed under monitored anesthesia care (MAC) or general anesthesia (GA). In this trial we will investigate the impact of anesthesia (CS vs GA) on the neurologic outcome of the patients.

Organizational Data

- DRKS-ID: **DRKS00006801**
- Date of Registration in DRKS: **2014/10/13**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2014-344-f-S , Ethik-Kommission der Ärztekammer Westfalen-Lippe und der med. Fakultät der Westfälischen Wilhelms-Universität Münster**

Secondary IDs

- Sponsor-ID: **05-AnIt-14**

Health condition or Problem studied



- ICD10: **I64 - Stroke, not specified as haemorrhage or infarction**
- ICD10: **I63 - Cerebral infarction**

Interventions/Observational Groups

- Arm 1: **control group: general anesthesia**
- Arm 2: **Intervention group: sedation**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Active control (effective treatment of control group)**
- Purpose: **Prognosis**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

neurologic outcome (modified Rankin Score mRS) 3 months after stroke

Secondary Outcome

- **neurological outcome at discharge**
- **mortality (in hospital, after 3 months)**
- **length of ICU stay**
- **door to first pass**
- **rate of recanalization**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Klinik für Anästhesiologie, operative Intensivmedizin und Schmerztherapie, Münster**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/12/09**
- Target Sample Size: **130**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **85 Years**

Additional Inclusion Criteria

- **acute ischemic stroke with the indication for endovascular clot retrieval**
- **anterior circulation stroke**
- **acute focal neurological deficit**
- **spontaneous breathing**

Exclusion criteria

- **intracerebral tumor**
- **intracerebral hemorrhage**
- **severe stroke (NIHSS > 25)**
- **seizure at beginning of treatment**
- **significant trauma within the last 3 month**
- **intracranial surgery in medical history**
- **blood glucose < 50 mg/dl or > 400 mg/dl**
- **alcohol abuse**
- **chronic pain**
- **severe systemic infections**
- **dementia (mRS>=3)**

Addresses

- **Primary Sponsor**

**Universitätsklinikum MünsterKlinik für Anästhesiologie, operative
Intensivmedizin und Schmerztherapie
Albert-Schweitzer-Campus 1, A1
48149 Münster**

Primary Sponsor

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

Institutional budget, no external funding (budget of sponsor/PI)

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Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.