# ISCHEMIA TRIAL

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23094

**Source**
NTR

**Brief title**
ISCHEMIA

**Health condition**

aneurysmal subarachnoid hemorrhage

### Sponsors and support

**Primary sponsor:** Academic Medical Center
**Source(s) of monetary or material Support:** sponsor

### Intervention

### Outcome measures

**Primary outcome**

in hospital mortality

**Secondary outcome**

Peri-procedural complications, hemorrhagic complications, outcome using modified Rankin Scale, health costs

# Study description

**Background summary**

Rationale: For long, delayed cerebral ischemia (DCI) was thought to be caused by subarachnoid blood-induced vasospasm. Growing experimental and clinical evidence now suggest activation of several (intravascular) pathophysiological pathways, affecting the microcirculation. Recently, in a retrospective analysis of our Academic Medical Center (AMC) aneurysmal subarachnoid hemorrhage (aSAH) patient registry, we gained new insight into the possible beneficial effect of high-dose low-molecular weight heparin (LMWH): lower in-hospital mortality and more discharge to home. We therefore, hypothesize that treatment with high-dose LMWH not only reduces in-hospital mortality, but can also improve the clinical outcome in aSAH patients after six months, and aim to determine the effect of high-dose LMWH in a randomized controlled trial: 'Improving outcome in SubaraChnoid HEMorrhage wIth NAdroparin' (= ISCHEMIA-study).

Objective: Our primary objective is to evaluate whether aSAH patients treated with high-dose (i.e. therapeutic) LMWH have lower in-hospital mortality rate, compared to aSAH patients treated with conventional (prophylactic) dose LMWH. Secondary objectives are whether high-dose LMWH improves clinical outcome at six months, reduces complications during admission and non-home discharge location, improves quality of life and cognitive functioning at six months, and reduces health care costs.

Study Design: A single-center, prospective, phase III randomized, controlled, clinical trial (RCT) in patients with an aSAH treated with endovascular coiling of the causative aneurysm.

Study population ASAH patients ≥18 years old, admitted to the Academic Medical Center (AMC), in whom the causative aneurysm is treated with endovascular coiling.

Intervention: After the causative aneurysm is coiled, patients will be randomized into two groups: (1) Intervention group: switch standard-dose to high-dose (=therapeutic) LMWH; nadroparin, twice daily 5700 AxaIU, subcutaneously, starting within 24 hours after coiling and continued until discharge; (2) Control group: continue standard-dose (=thrombosis prophylaxis) LMWH; nadroparin, once daily 2850 AxaIU, subcutaneously, continued until discharge.

Main study parameters/endpoints: In-hospital mortality rate; clinical outcome after six

months' follow-up, measured with the modified Rankin Scale; complications during admission (hemorrhagic complications, DCI, shunt-dependent hydrocephalus, seizures, delirium and hospital-acquired nosocomial infections); discharge location; cerebral infarctions on MR-imaging six months after SAH, not attributable to endovascular treatment or ventricular catheter placement; quality of life (EQ-5D) and cognitive functioning (Montreal Cognitive Assessment ) at six months; health care costs.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: An aneurysmal subarachnoid hemorrhage is a life-threatening form of stroke: mortality amounts to 32%-39%, and 50% of the survivors experience a permanent disability. On admission, approximately half of the patients is in a good neurological condition (grade I), and one in 10 presents comatose (grade V). Nowadays, 80% of patients is treated endovascularly by the interventional neuroradiologist. After endovascular coiling of the causative aneurysm, all subjects, regardless of neurological grade on admission, will be randomly allocated to high-dose (therapeutic) LMWH or conventional (prophylactic) LMWH therapy. Hereby, study results will be generalizable to the whole aSAH population treated with endovascular coiling. The safety of this medication in these patients has been confirmed in our retrospective study; specifically, there was no increase in hemorrhagic events. The expected benefit is large as half of the patients is younger than 55-years-old, and reduction in death, or disability, leading to improved clinical outcome, could significantly decrease the loss of productive life years, with enormous economic and social impact.

**Study design**

Baseline, 3 and 6 months

**Intervention**

High-dose nadroparin

# Contacts

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# Eligibility criteria

## Inclusion criteria

Adult
Occluded aneurysm

## Exclusion criteria

untreated aneurysm

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-01-2018 |
| Enrollment: | 80 |
| Type: | Anticipated |

# Ethics review

Not applicable
Application type: Not applicable

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL6900 |
| NTR-old | NTR7087 |
| Other | : Informatie niet aangeleverd door onderzoeker |

# Study results