Improving the outcome of chronic subdural hematoma by embolization of the middle meningeal artery (ELIMINATE).

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Primary: To evaluate whether additional embolization of the middle meningeal artery after surgery for cSDH reduces the recurrent surgery rate. Secondary: to evaluate whether the use of middle meningeal artery embolization after surgical treatment in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON55323

Source
ToetsingOnline

Brief title
Embolization in chronic subdural hematoma

Condition

- Central nervous system vascular disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
bleeding in the subdural space, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic subdural hematoma, Embolization, Middle meningeal artery, Recurrent surgery

Outcome measures

Primary outcome

The difference in reoperation rate between the control group and the

intervention group.

Secondary outcome

1. Volume/size of cSDH at eight, 16 and 24 weeks on follow-up CT scan of the

head.

2. Number of procedure related complications during hospital admission and 24

week follow-up.

3. Neurological impairment at eight, 16 and 24 weeks, measured with the

modified National Institutes of Health Stroke Scale (mNIHSS) score and

Markwalder score.

4. Functional outcome at 24 weeks, measured with the modified Rankin Scale

(mRS) score.

5. Cognitive functioning at eight, 16 weeks and 24 measured with the Montreal

Cognitive Assessment (MOCA) test and m-TICS.

6. Mortality at 24 weeks.

7. Performance in activities of daily living at 24 weeks, measured with the

Barthel Index.

8. Quality of life at 24 weeks, measured with the

a. Short Form Health Survey (SF-36) questionnaire;

b. five dimensional EuroQol (EQ-5D-3L) questionnaire.

9 Care and health-related costs during the 24 week study period, measured with

the

a. Medical Consumption Questionnaire (iMCQ);

b. Productivity Cost Questionnaire (iPCQ).

Study description

Background summary

Chronic subdural hematoma (cSDH) is a relatively frequent occuring disease in neurosurgical practice. cSDH usually develops after minor head trauma and is most common in the elderly. The majority of cSDH patients (80%) need to undergo surgery in order to relieve symptoms. There are different surgical methods, but 90% of the time burr-hole craniostomy (BHC) is used. One or two holes on the affected side of the skull are drilled and the hematoma is drained. This immediately relieves patients of their (life-threatening) symptoms. However, surgery is costly, and in these often frail patients, with multi-morbidity, comes with significant risks for future cognitive functioning, and therefore loss of independence. Furthermore, recurrence rates after surgery range from about 10-30%, resulting in even more operations.Therefore, the optimal treatment for cSDH remains a *burning clinical question* for which neurologists and neurosurgeons do not have evidence-based answers.

In order to come up with a solution, multiple different therapies have been proposed. Embolization of the middle meningeal artery is by far the most striking one.The goal of embolization is to devascularize the subdural membranes to a sufficient extent such that the balance is shifted from the continued leakage and accumulation of blood products towards reabsorption, hereby reducing postoperative recurrence and ultimately morbidity and mortality. The usage of embolization in cSDH patients was introduced in 2000. and since then there have been multiple case reports, case series and cohort studies that have investigated its safety and effectiveness. The findings of these studies studies were summarized in recent systematic reviews about embolization which highlight its potential in the management of cSDH patients. Apart from the lower recurrence (2.0 - 5.0% in all cases) and complication rate

(0 - 2.1% in all cases), also additional benefits such as the minimally invasive character of the procedure are exciting. Nevertheless it is stressed that these results are based on studies with moderate quality and a small sample size.

Without studying the efficiacy and safety of embolization in larger scaled randomized trials, the question if the addition of embolization really improves recurrence rates, functional outcome and complication rate, will remain unanswered. By elucidating these topics the treatment of cSDH patients can be improved significantly.

Study objective

Primary: To evaluate whether additional embolization of the middle meningeal artery after surgery for cSDH reduces the recurrent surgery rate. Secondary: to evaluate whether the use of middle meningeal artery embolization after surgical treatment in symptomatic cSDH patients increases quality of life (SF-36 and the EQ-5D-5L), performance in activities of daily living (Barthel Index), functional outcome (mRS), cognitive functioning (MOCA/m-TICS) and reduces mortality, occurrence of complications, recurrence rate, size and volume of the hematoma, neurological impairment (mNIHSS and Markwalder score) and the use of care and health-related costs (iMCQ and iPCQ).

Study design

Multicentre, randomized controlled open-label superiority trial.

Intervention

Peri-operative embolization until 72 hours after surgery.

Study burden and risks

Symptomatic cSDH patients will undergo peri-operative embolization of the middle meningeal artery until 72 hours after surgical treatment. Complications are monitored during hospital admission and follow-up. Radiological and clinical follow-up is at eight, 16 and 24 weeks post-intervention with a CT-scan of the head and assessment of mRS, MOCA/m-TICS, mNIHSS, Markwalder score, SF-36, EQ-5D-5L, Barthel Index, iMCQ and iPCQ. Standard care after surgery entails outpatient follow-up with on average two CT-scans, indicated by clinical signs and symptoms. For this study a CT-scan will be performed routinely at eight, 16 and 24 weeks post-intervention; embolization, on average one CT-scan, and questionnaires are extra for this study. Potential complications of endovascular embolization are thromboembolic events which occur in <0.3%. Patients may benefit from the study if embolization proves to be effective to prevent recurrent surgery, thereby lowering the morbidity and

mortality rate and increasing quality of life.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Has a head-CT or MRI confirmed diagnosis of cSDH
- Primary surgical treatment based on clinical symptoms (progressive neurological deficits)

Exclusion criteria

- Significant contraindication to angiography (eg. allergy for contrast,

inability to lay still);
- Structural causes for subdural haemorrhage, e.g. arachnoid cysts, cortical vascular malformations and a history of cranial surgery <1year
- Inability to obtain informed consent from the patient or legal representative (when the patient has a depressed level of consciousness), including language barrier;
- Monocular blindness contralateral to hematoma;
- Surgical treatment with craniotomy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-12-2020
Enrollment:	170
Type:	Actual

Ethics review

Approved WMO Date:	30-07-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	19-12-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT04511572
CCMO	NL71901.018.20