The Dutch ICH Surgery Trial pilot study; minimally-invasive endoscopy-guided surgery for spontaneous intracerebral hemorrhage

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1. To study safety, feasibility and technical effectiveness of minimally-invasive endoscopy-guided surgery for treatment of supratentorial ICH; 2. To estimate the potential effect of minimally-invasive endoscopy-guided surgery on functional outcome…

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

Summary

ID

NL-OMON46374

Source
ToetsingOnline

Brief title
DUTCH-ICH Surgery Trial pilot study

Condition

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

Synonym
Brain haemorrhage; Intracerebral hematoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Nederlandse Hartstichting en via bedrijven unrestricted grants,Penumbra Inc

Intervention

Keyword: Endoscopy, Intracerebral hematoma, Minimally invasive neurosurgery

Outcome measures

Primary outcome

The main outcome parameters will be safety (death within 24 hours; 7-day procedure related complications; 7-day mortality, 30 day mortality) and technical effectiveness (proportional volume reduction; proportion of patients with clot volume reduction *60% and *80%; proportion of patients with remaining clot volume *15mL).

Secondary outcome

Secondary parameters will be the effect of surgery on 90 day functional outcome (modified Rankin Scale) in comparison with the matched control patients with ICH, on NIHSS at one week and on functional outcome after 180 days.

Study description

Background summary

Intracerebral hemorrhage (ICH) accounts for 15-20% of all strokes in Western Europe, and contributes profoundly to mortality and disability. Thirty day case fatality is 40% and of those surviving, only few gain independence. Except for stroke unit care and early blood pressure lowering there is currently no treatment of proven benefit. Important predictors of poor outcome are increasing age, decreasing Glasgow Coma Scale score, increasing ICH volume, presence of intraventricular hemorrhage, and deep or infratentorial location. In addition, secondary injury, due to development of edema and an inflammatory

response, contribute to disability and death. Surgical treatment, mostly comprising craniotomy, has so far not been proven effective. In the largest trials STICH I and II, the median time to treatment was more than 24 hours, which may be an important explanation for the lack of treatment effect.
We hypothesize that early minimally-invasive endoscopy-guided surgery improves outcome in patients with spontaneous supratentorial ICH.

Study objective

1. To study safety, feasibility and technical effectiveness of minimally-invasive endoscopy-guided surgery for treatment of supratentorial ICH; 2. To estimate the potential effect of minimally-invasive endoscopy-guided surgery on functional outcome in patients with supratentorial ICH.

Study design

A multicentre, prospective, intervention study, phase II.

Intervention

Minimally-invasive endoscopy-guided surgery within 8 hours of symptom onset, in addition to standard medical management.

Study burden and risks

Minimally-invasive endoscopy-guided surgery has been shown to carry limited risks and is of potential benefit to improve outcome. The main risks of surgery consist of intracranial hemorrhage (rebleeding, subdural hematoma), operation site infection, and seizures. The burden will consist of performance of 3 additional CT scans within in the first week after ICH and a telephone interview for outcome assessment after 3 and 6 months. Because patients with ICH may present with aphasia or decreased consciousness, we will include competent and non-competent patients; in the latter informed consent will be obtained from the patients* representatives.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific

Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age * 18
2. NIHSS * 2
3. Supratentorial ICH confirmed by CT, without a CTA confirmed causative vascular lesion (eg aneurysma, AVM, DAVF, CVST).
4. Minimal lesion size 10 mL
5. Intervention can be started within 8 hours from symptoms onset; or for controls presentation within 8 hours of symptom onset.
6. Written informed consent

Exclusion criteria

1. Pre-stroke disability, which interferes with the assessment of functional outcome at 90 days, i.e. mRS > 2
2. Causative vascular lesion (e.g. aneurysm, AVM, DAVF, CVST) on CTA or other known underlying cause (e.g. tumor, cavernoma)
3. Untreated coagulation abnormalities, including INR>1.3 (point of care measurement allowed) and treatment with oral thrombin or factor X antagonists; patients on vitamin K antagonist can be included after correction of the INR.
4. Current known severe infection for which antibiotic treatment at time of ICH symptom onset
5. Patient moribund (eg. coning, bilateral dilated unresponsive pupils)

6. Pregnancy (note: most patients will be beyond child bearing age; if not a pregnancy test is mandatory).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2018
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	18-05-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-10-2018
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22738
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT03608423
CCMO	NL63100.078.17
OMON	NL-OMON22738