Swiss trial of decompressive craniectomy versus best medical treatment of spontaneous supratentorial intracerebral hemorrhage: a randomized controlled trial

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The primary objective of this randomized controlled trial is to determine whether decompressive surgery and best medical treatment in patients with spontaneous ICH will improve outcome compared to best medical treatment only. Secondary objectives...

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

Summary

ID

NL-OMON50259

Source
ToetsingOnline

Brief title
SWITCH: decompressive surgery for spontaneous intracerebral hemorrhage

Condition

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

Synonym
spontaneous intracerebral hemorrhage / brain bleeding

Research involving

Human

Sponsors and support

Primary sponsor: Inselspital, universitätsspital Bern
Source(s) of monetary or material Support: Swiss National Science Foundation;Swiss Heart Foundation;Inselspital Stiftung

Intervention

Keyword: Decompressive craniectomy, Intracerebral hemorrhage

Outcome measures

Primary outcome

Primary outcome is the composite of mortality or dependency (mRS score 5

[severe dependency] or 6 [death]) at 180 days ± 14 days. Primary endpoint (mRS)

will be assessed by a structured telephone interview (180 days ± 14 days post

randomization)

Secondary outcome

Composite of mortality or dependency

- mRS score 5 [severe dependency] or 6 [death]) at 30 ± 7 days by telephone

interview.

Mortality

- Mortality will be assessed by using the mRS at 7 days (if discharged earlier,

this will be assessed at discharge), 30 ± 7 days, 180 ± 14 days and at 12

months ± 30 days by telephone interview. If patients/relatives do not respond

the general practitioner or treating physician will be contacted.

Dependency

- Dependency is assessed using the mRS at 7 days (if discharged earlier, this will be assessed at discharge), 30 ± 7 days, 180 ± 14 days and at 12 months ± 30 days by telephone interview.

mRS score of 0-3 versus 4-6, at 30 ± 7 days, at 180 ± 14 days and at 12 months ± 30 days

- This is a secondary analysis of the mRS.

Categorical shift in modified Rankin Scale (mRS) score at 180 ± 14 days

- This is a secondary analysis of the mRS.

QoL:

- QoL will be assessed at 180 ± 14 days and at 12 months ± 30 days after randomization using the EuroQoL questionnaire. It will be assessed during a telephone interview.

National Institutes of Health Stroke Scale (NIHSS)

- NIHSS will be assessed at baseline, at 7 days (if discharged earlier, this will be assessed at discharge) and 180 ± 14 days, by a trained neurologist or trial nurse.

Glasgow Coma Scale (GCS)

- The GCS will be assessed at baseline, at discharge and during an outpatient visit 180 ± 14 days after randomization by a trained neurologist or trial nurse.

Length of hospital stay

- Hospitalization will include only the initial hospitalization and treatment. Assessment is based on medical records and will be performed 6 months after study inclusion.

Residential care

- The status of residential care will be assessed based on medical records and questioning of the patient and/or relatives at 180 ± 14 days and at 12 months by telephone interview.

Safety

- Safety outcomes will be evaluated according to the details given in Section 10 of the study protocol.

Size of infarction

- The size of infarction/brain damage will be measured volumetrically in the imaging core lab using the 6 month imaging (CT/MRI). Therefore, the pseudo-anonymized CT/MRI scan of visit 7 will be sent on CD-ROM to the trial coordinator.

Time from symptom onset to randomization

- Onset of symptoms and time of randomization are retained (date and time) in the case report form (CRF).

Radiological outcome measures

- The midline shift will be centrally assessed and reviewed in the imaging core lab using the pre-randomization imaging (CT/MRI). Therefore the pseudo-anonymized CT/MRI scan of visit 1 will be sent on CD-Rom to the trial coordinator.

- Hematoma enlargement

- Presence of spot sign on brain imaging

Surgical procedure

- EVD

- ICP

- CSF shunt

- DC

- Surgical removal of hematoma

Study description

Background summary

Spontaneous intracerebral hemorrhage (ICH) remains a devastating disease with mortality rates up to 52% at 30 days. It is a major public health problem with an annual incidence of 10-30 per 100*000 population, accounting for 2 million (10-15%) of about 15 million strokes worldwide each year. The strategy of decompressive craniectomy (DC) is beneficial in patients with malignant middle cerebral artery (MCA) infarction. Based on the common pathophysiological mechanisms of these two conditions, this procedure is also frequently performed in patients with ICH, but is has not yet been investigated in a randomized trial.

Study objective

The primary objective of this randomized controlled trial is to determine whether decompressive surgery and best medical treatment in patients with spontaneous ICH will improve outcome compared to best medical treatment only. Secondary objectives are to analyze mortality, dependency and quality of life. Safety endpoints are to determine cause of any mortality and the rate of medical and surgical complications after DC compared with best medical treatment alone.

Study design

Multicenter randomized (1:1) controlled, parallel group trial

Intervention

All patients in the treatment group will receive decompressive hemicraniectomy with a diameter of at least 12 cm and best medical treatment according to institutional guidelines and a surgical protocol.

Study burden and risks

The role of hematoma evacuation in the treatment of ICH is still unclear, and it is also unknown whether decompressive craniectomy (DC) in the treatment of ICH is beneficial, even though DC is a standard approach in patients with malignant MCA infarction and in patients with ICH due to sinus venous thrombosis, herpes encephalitis and brain trauma. According to the literature, DC in conjunction with hematoma evacuation improved outcome, yet the reported DCs did not achieve modern standards and hematoma evacuation for deep seated hematoma has not been proven beneficial for the patient. The Bern researchgroup analyzed DC in ICH in a recent retrospective series and showed a reduced mortality, but no statistically significant improvement of outcome at 3 months according to the mRS. However, this retrospective trial was underpowered to show a potential benefit; there was no difference between the surgical and conservative groups. Despite this lack of statistical significance, a potential benefit for patients was the increased survival rate without serious complications; surgery was not associated with a higher rate of mortality or morbidity. After these results were published one new pre-clinical trial, one meta-analysis, and one original contribution were published, all dealing with DC in ICH without hematoma evacuation. All studies came to the conclusion that the risk/benefit ratio is favorable and mandates a randomized controlled trial. DC is a standard approach and risks associated with DC are well known. It is a comparatively simple procedure that is performed in every neurosurgical center. Guresir et al. investigated the rate of complications in DC; their analysis distinguished between complications related to the DC and those related to cranioplasty. The most common complications related to DC were wound healing disturbances (3.5%), abscess (2.6%), CSF fistula (0.6%) and epi/subdural hematoma (2.1%). Complications related to cranioplasty were wound healing

disturbances (6.1%), abscess (2.6%), CSF fistula (1%), epi/subdural hematoma (4.1%), hygroma (1.5%) and bone flap dislocation (0.5%).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age: >=18 to <=75 years
- Deep ICH (basal ganglia or thalamus) that may extend into cerebral lobes, ventricles or subarachnoid space
- Acute stroke syndrome due to a spontaneous ICH
- NIHSS score of >=10 and <=30
- Glasgow coma scale (GCS) >7 and <14
- Randomization within 66 hours after ictus
- Surgical treatment not later than 6 hours after randomization

- Volume of hematoma >=30 ml and <=100 ml

Exclusion criteria

- ICH due to known or suspected structural abnormality in the brain (e.g., intracranial aneurysm, brain arteriovenous malformation, brain tumor) or brain trauma, or previous stroke thrombolysis
- Cerebellar or brainstem hemorrhage
- Exclusive lobar hemorrhage
- Moribund patients (GCS 3-7)
- Patient has a signed do-not-treat statement
- Known advanced dementia or significant pre-stroke disability
- Concomitant medical illness that would interfere with outcome assessment and follow-up
- Pregnancy
- Prior major brain surgery within <6 month or prior DC
- Foreseeable difficulties in follow-up due to geographic reasons
- Known definite contraindication for a surgical procedure
- A very high likelihood that the patient will die within the next 24 hours on the basis of clinical and/or radiological criteria
- Previous participation in this trial or in another ongoing investigational trial
- Prior symptomatic ICH
- ICH secondary to thrombolysis
- Bilateral areactive pupils

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: Completed

Start date (anticipated):	11-01-2017
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	04-03-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	01-08-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-06-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-09-2020
Application type:	Amendment
Review commission:	METC NedMec

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	NCT02258919
CCMO	NL53420.041.15

Study results

Date completed: 17-06-2023

Actual enrolment: 13

Summary results
Trial ended prematurely