Swiss Trial of Decompressive Craniectomy versus Best Medical Treatment of Spontaneous Supratentorial Intracerebral Hemorrhage (SWITCH): A Randomized Controlled Trial

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Sponsor-investigators
Prof. Dr. med. Jürgen Beck
Department of Neurosurgery
Chairman: Prof. Andreas Raabe
University Hospital Bern
Inselspital
CH-3010 Bern
juergen.beck@insel.ch

Prof. Dr. med. Urs Fischer
Department of Neurology
Chairman: Prof. Claudio L. Bassetti
University Hospital Bern
Inselspital
CH-3010 Bern
urs.fischer@insel.ch

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Decompressive craniectomy from three different perspectives

Introduction
Spontaneous intracerebral hemorrhage (ICH) is a major public health problem affecting 2 million people worldwide each year. It is a devastating disease; up to half of the affected patients die within 30 days and the majority of survivors are permanently handicapped.

Why is ICH so devastating?
ICH is the most severe form of stroke. The hemorrhage damages the brain both directly, by destruction of brain tissue, and indirectly by increasing the pressure within the brain.

Previous trials have investigated surgical removal of the hematoma. The results were disappointing and the two most recent carefully performed and important trials (STICH I and STICH II) failed to show a benefit after surgical removal of the hematoma. Surgical removal of the hematoma is thought to be ineffective due to additional trauma to the brain. Therefore new concepts are urgently needed to find treatment solutions for this devastating disease.

New concept
Decompressive craniectomy decreases intracranial pressure without further damage to the vulnerable brain. During this procedure the bone of the skull is removed, enabling the brain to expand and thereby reducing intracranial pressure. Decompressive craniectomy is a well-established treatment in patients with large ischemic strokes (major trials: DESTINY, HAMLET, DECIMAL).

Neurocenter Bern
The Neurocenter Bern is a leading international neurovascular center with the largest number of highly-specialized interventions in Switzerland, including the endovascular clot retrieval after ischemic stroke. In a combined effort between centers in Bern and Geneva, the new treatment concept of decompressive craniectomy after intracerebral hemorrhage has already been successfully applied and results have been published in a major international journal (Stroke) in 2012. This Swiss trial showed that the new treatment is feasible and safe. This trial showed promising effects with regard to mortality and outcome. Based on these results and lively discussions among specialists in Switzerland, we planned to conduct a prospective randomized trial on this new treatment concept.

SWITCH – the protocol

Aim of the study
The primary aim of this trial in patients with acute intracerebral hemorrhage (ICH) is to show that best medical treatment plus decompressive craniectomy (DC) is superior to best medical treatment alone with respect to the morbidity and mortality of the patients.

Study Protocol
The study will be conducted in major European stroke centers.

Key Inclusion Criteria
- Age ≥18 to ≤75 years
- Acute stroke syndrome due to a spontaneous ICH
- Haemorrhage into basal ganglia or thalamus that may extend into cerebral lobes, ventricles or subarachnoid space
- Glasgow coma scale (GCS) <14 and ≥7
- NIHSS ≥10 and ≤20
- Surgical treatment within 72 hours after ictus
- Volume of hematoma ≥30 ml and ≤100 ml

Key Exclusion Criteria
- Intracranial aneurysm, brain arteriovenous malformation, brain tumor, brain trauma, stroke thrombolysis
- Cerebellar or brainstem hemorrhage
- Exclusive lobar hemorrhage
- Mortibund patients (GCS 3-7)

Treatmet Groups
SWITCH will compare early decompressive craniectomy (DC) plus best medical treatment versus best medical treatment alone.

All patients in the treatment group will receive a decompressive craniectomy (DC) with a diameter of at least 12 cm. Best medical treatment for both groups is consistent with the current American Heart Association/American Stroke Association (AHA/ASA) guidelines.

Outcome
The primary outcome is the composite of mortality or dependency at 6 months after treatment (mRS 5 and 6).

Secondary outcome parameters will be:
- Mortality
- Health-related quality of life (HRQoL)
- Neurological impairment (National Institute of Health Stroke Scale)
- Complication rate

Sample Size / duration of the trial
As shown in our recent feasibility study (Fung et al. 2012) the proportion of patients with an unfavourable outcome (mRS 5-6) was 0.53 in the control group. Thus, a total sample size of 300 patients will provide over 82% power at a two-sided level of 0.05 to detect a relative risk reduction of 33% using a Chi-squared test.

With at least 4 major stroke centers participating in Switzerland (so far: Bern, Geneva, Lucerne, Lugano) and many European sites (so far: Aachen, Amsterdam, Barcelona, Berlin, Bonn, Düsseldorf, Erfurt, Erlangen, Essen, Frankfurt, Freiburg, Giessen, Gottingen, Helsinki, Innsbruck, Kassel, Liebeck, Mannheim, Mainz, Munich, Münster, Sevilla, Utrecht, Würzburg) it is clearly feasible to conduct this trial in the planned time period. Randomization of the patients started in October 2014 and will end in December 2019. After completion of the follow-up period of 6 months, the primary outcome data will be collected in June 2020, with publication of the results anticipated in December 2020.

Financing
The Swiss National Science Foundation has approved a grant over CHF 520,000 in September 2013. In addition funds were granted from the Swiss Heart Foundation (CHF 100,000) and Inselspital Bern (CHF 80,000).

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Wu et al., Stroke, American Heart and Stroke Association, 2017

Discussion

Here is what literature says about our concept:

“... DC ameliorates the mass effect exerted by the ICH plus the perihematomal edema (PHE)”


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3D-computed tomography (CT) reconstruction of the skull after decompressive craniectomy from three different perspectives

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