SWISS TRIAL OF INITIAL DECOMPRESSIVE CRANIECTOMY VERSUS BEST MEDICAL TREATMENT OF SPONTANEOUS SUPRATENTORIAL INTRACEREBRAL HEMORRHAGE - A RANDOMIZED TRIAL (SWITCH)

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Background

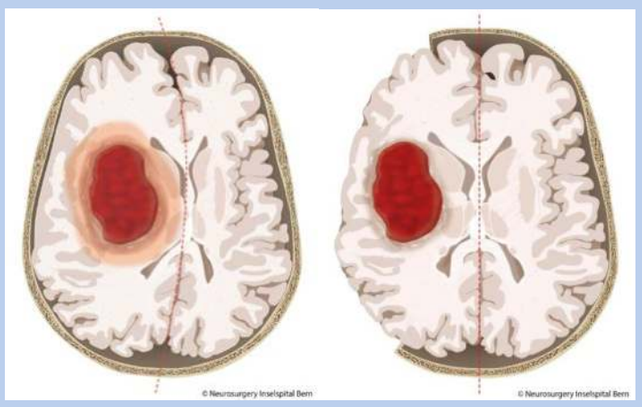


Figure 1: Schematic drawing of hematoma (red) and space-occupying effect before (left) and after (right) decompressive craniectomy

Spontaneous intracerebral hemorrhage (ICH) remains a devastating disease and a major public health problem, accounting for 10-15% of the 15 million strokes worldwide. Despite giving best medical treatment (BMT), one-third of patients with ICH die within one month and the majority of survivors remain handicapped.

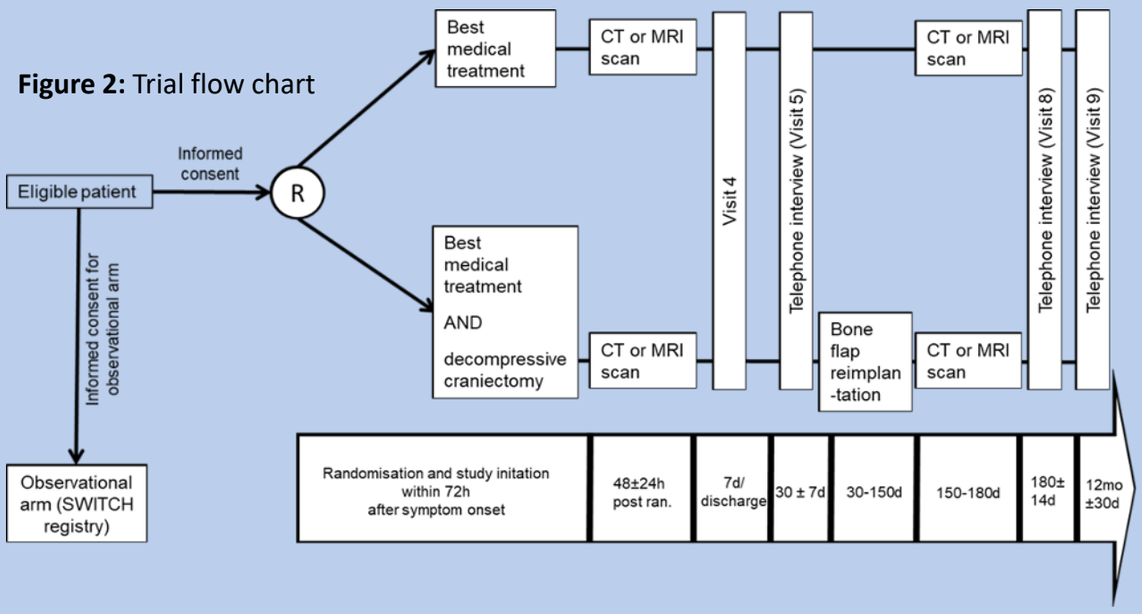
Decompressive craniectomy (DC) was shown to be beneficial in patients with various diseases including malignant middle cerebral artery (MCA) infarction, but in ICH, DC without hematoma evacuation has only been evaluated in small retrospective studies with a trend towards reduced mortality and improved outcome. Whether DC, compared to BMT, may be more beneficial to ICH patients by decreasing perihematomal brain tissue pressure is still a matter of debate and the purpose of this trial.

SWITCH was initiated in October 2014.

Methods

- SWITCH is an international, multicenter, randomized-controlled, parallel group trial
- 300 patients will be randomly assigned (1:1) either into the experimental arm (DC + BMT) or in the control arm (BMT alone).
- Main inclusion criteria: spontaneous deep-seated ICH, age ≥ 18 to ≤ 75 years, severe neurological deficit (NIHSS ≥10 and ≤ 30, GCS >7 and < 14), and hematoma volume between 30 and 100 ml.
- Primary outcome: composite of mortality or dependency (modified Rankin scale 5 or 6) at 6 months.

Figure 2: Trial flow chart



Results

Recruitment:

- 32 sites in 7 European countries (Switzerland, Germany, Austria, the Netherlands, Finland, Spain, France) are currently participating in the trial
- 73 patients were successfully randomized in the trial so far
- The current recruitment rate is 0.66 patients per center per year
- Less than 5% of ICH patients are eligible for the trial

Demographic results of randomized patients:

- 73 patients: 36 DC and 37 BMT
- 17 females and 56 males
- 1 drop out
- 17 patients died
- Age (mean): 59.4 years (±10.8)
- GCS (median): 10 (±1.69)
- NIHSS (median): 18 (±3.89)
- Volume (median): 53 cc (±18.38)

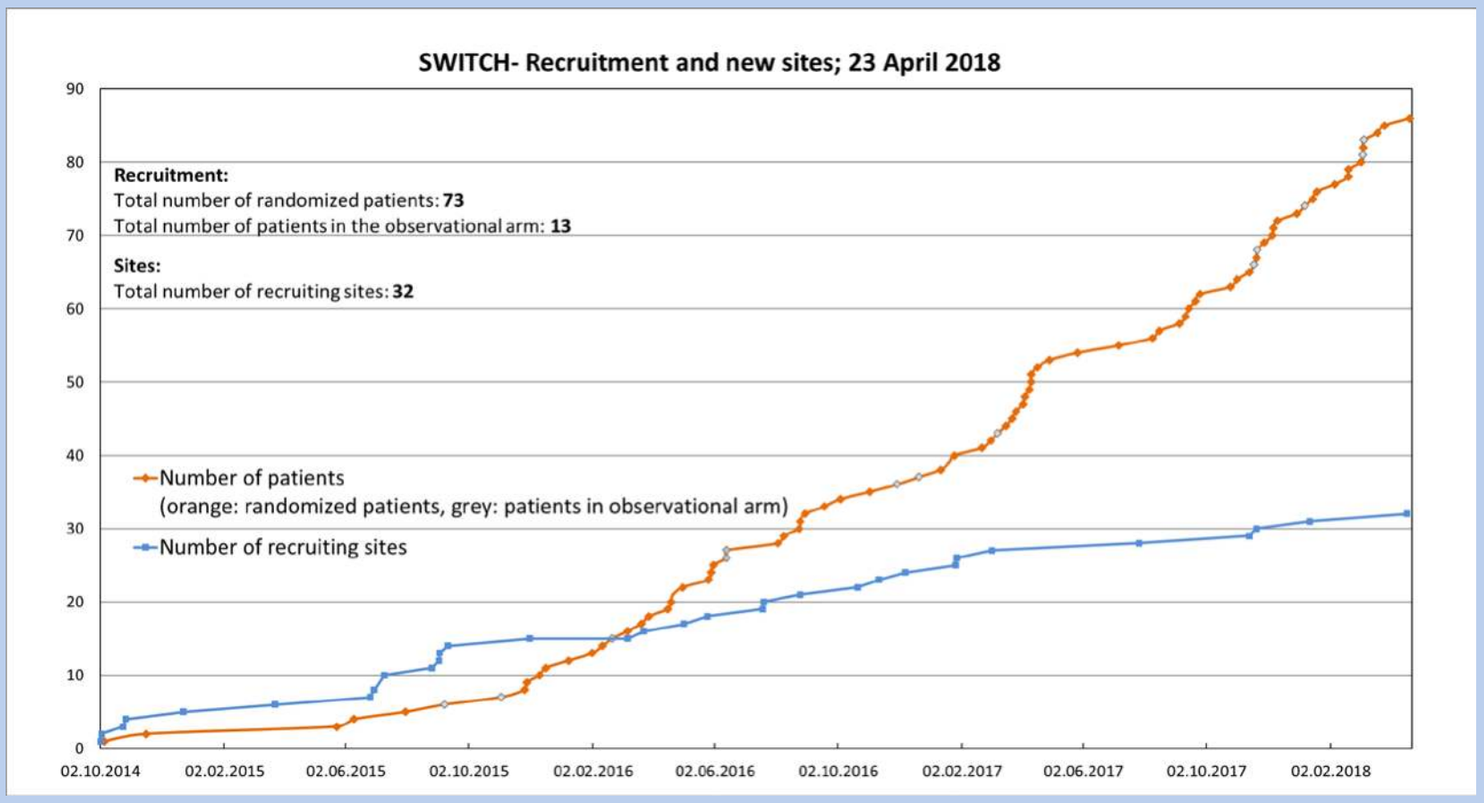


Figure 3: Recruitment of patients and new sites for the SWITCH trial

Conclusions

SWITCH tries to answer the clinically relevant question whether decompressive craniectomy plus best medical treatment is of any benefit compared to best medical treatment alone in patients with spontaneous ICH, which could impact future management of this disease.

Since its start in 2014, SWITCH developed to a large international consortium in order to augment patient recruitment and now includes 31 participating sites over six European countries. We are convinced that maintaining a high recruitment rate is crucial for the successful completion of the trial and are hence always welcoming additional centers. Please let us know if you are interested!

More information: **www.switch-trial.ch**

SWITCH