



Newsletter February 2018

Clinical Equipoise and its implications for SWITCH

Clinical Equipoise is the genuine uncertainty whether a treatment is beneficial over another.



We do not know whether decompressive surgery in ICH is of any benefit.



This is the reason why we run this trial!

Dilemma: During the course of a trial investigators start to believe that one interventional arm is superior to the other. This alters patient management and recruitment.



But taking part in a trial should not change patient management.

Reasons:

- We still do not know which therapeutic option is superior.
- Even if more patients stay alive in one arm, we do not know whether they do not end up institutionalized with severe disability.

Solution: Eligible patients must be randomized and treated accordingly to achieve valid trial results! Otherwise we might jeopardize the management of ICH patients, for whom there still is not much to offer.



Examples from our clinical experience:

- My consultant and my supervisor think that decompressive surgery is not beneficial anyway. So why randomize?
- The patient is randomized to the conservative arm (best medical treatment) and his neurological status deteriorates. We are then allowed to operate, right?
- A young patient met all inclusion criteria but had a midline shift. There is a high probability that he will die. Could we have included him in the trial and still operate if he would have been allocated to the conservative arm (best medical treatment)?

There is no evidence that decompressive surgery improves outcome in patients with ICH, even if they deteriorate and even if they have a midline shift. Therefore all patients fulfilling the inclusion criteria of SWITCH should be randomized!

The non-inclusion of eligible patients has a major impact on the results of the trial by altering the composition of the included trial cohort.



Current patient accrual (31.01.2018)

Randomized trial: 65

Observational arm: 11

Top recruiting sites

1. Bern (11 patients randomized)
2. Berlin (9 patients randomized, 1 patient in observational arm)
3. Helsinki (8 patients randomized, 1 patient in observational arm)
4. Aachen (6 patients randomized)
5. Giessen (4 patients randomized, 3 patients in observational arm)

SWITCH sites

Currently we have 31 sites open for the recruitment of patients.

Recruiting	Aachen, Amsterdam, Barcelona – Bellvitge Hospital, Barcelona – Santa Creu i Sant Pau Hospital, Bern, Berlin, Bonn, Düsseldorf, Erlangen, Erfurt, Essen, Frankfurt, Freiburg, Geneva, Giessen, Göttingen, Helsinki, Innsbruck, Kassel, Linz, Madrid, Mainz, Mannheim, München, Münster, Lübeck, Lucerne, Lugano, Sevilla, Utrecht, Würzburg
Coming soon	Paris, Créteil, Caen, Edinburgh
Planned	Siegen, Tübingen

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