Cooling in intracerebral hemorrhage (CINCH) trial

So far, the optimal treatment strategy for large primary intracerebral hemorrhage (ICH) is not clear, since both medical treatment and surgical intervention do not lead to improved functional outcome or survival rates. Based on promising experimental (Colbourne et al., 2009) and pilot clinical data on therapeutic hypothermia (TH) (Kollmar et al., 2010), the Cooling in INtraCerebral Hemorrhage (CINCH) trial has been designed to determine whether TH reduces perihemorrhagic edema and improves survival rates after large ICH. The CINCH trial is a German-Austrian multicenter, randomized controlled trial and will include 50 patients (age 18-65) with acute large primary ICH defined by location (basal ganglia or thalamus) and size (25 to 64ml on cranial CT). The patients will be randomly allocated between 6 and 18 hours after clinical ICH-symptom onset to two treatment groups: conservative medical treatment or TH. TH of 35°C will be initiated and maintained for 8 days by endovascular catheters and is followed by slow controlled rewarming. The primary outcome measures of the study are total lesion volume on CT (ICH plus perihemorrhagic edema on day 8±0.5 and day 11±0.5 after ICH) and mortality after 30 days. Secondary outcomes of interest include in-hospital mortality, mortality after 90 day, functional deficit as defined by the modified Rankin Scala (mRS) and Barthel-Index, serious adverse events (SAEs) associated to hypothermia and fever burden during ICU-treatment. The CINCH trial will produce the best available evidence on the effects of TH after large ICH. We anticipate that patients will benefit from TH at least concerning the mortality rate due to less perihemorrhagic edema and prevention of herniation.

The CINCH trial is an investigator driven trial and is performed in close collaboration with EUROHYP. PI is Rainer Kollmar, assistant professor of neurology and vice chair of the department of Neurology in the University hospital Erlangen at the Friedrich-

Alexander Universität Erlangen-Nürnberg. The trial has an independend data safety montoring board, a central imaging review (Prof. Arnd Dörfer, FAU Erlangen-Nürnberg) and an independent monitoring. Montitoring is performed from by the Center for stroke research Berlin, Erik Jüttler, who is Junior-professor of Neurology in the Charite hospital which is at the same time a part of the European Stroke Network.

The study will take part in the following Stroke and Neurointensive Care Centers:

Germany: Erlangen, Freiburg, Heidelberg, Berlin, Hannover, Jena, Halle, Leipzig, Minden.

Austria: Innsbruck, Lienz.

The trial is currently registered.

Protocol is available if requested by email to: rainer.kollmar@uk-erlangen.de