Treatment of intracerebral hemorrhage in patients on non-vitamin K oral anticoagulants with tranexamic acid (TICH-NOAC)

Principal Investigator**:**	PD Dr. med. Georg Kägi
Status:	ongoing, recruiting
Project Start:	2017
Project End:	unknown
Trial Design/Class:	randomized, placebo controlled phase-IIb/III multi-center treatment trial/ Class: C
Number of Patient:	109
Centers:	6 Swiss Stroke Centers (Basel, Bern, Luzern, Zurich, Aarau, St. Gallen)
Sponsor/Partner:	Stroke Center, Universitätsspital Basel, Basel, Switzerland, Prof. Dr. med. Philippe Lyrer, Prof. Dr. med. Stefan Engelter
Funding:	Universitätsspital Basel, Swiss National Science Foundation

Summary:

Novel, non-vitamin K antagonist oral anticoagulants (NOAC) are effective drugs for the prophylaxis and treatment of a variety of thromboembolic diseases such as stroke and prophylaxis in patients with atrial fibrillation. Intracerebral haemorrhage (ICH) is the most feared complication of the NOAC treatment (NOAC-ICH). Intracerebral haemorrhage in patients treated with anticoagulants (old anticoagulants such as vitamin K antagonists or NOAC) often have post-operative haemorrhages (= haematoma expansion, HE) in the early phase after the event, which is a poor prognostic factor. Overall, the prognosis in patients with cerebral haemorrhage under anticoagulants is poor with a high mortality rate (about 20%) and a high rate of patients with permanent neurological disability. Recently, specific reversal agents for NOACs have been developed, but there is no evidence-based treatment of NOAC cerebral haemorrhage, that has been shown to improve clinical outcome and prevent post-operative bleeding. Tranexamic acid is a drug known for >20 years that can be administered in many areas of medicine to stop bleeding, for example after accidents or during surgery. A large, multi-national study is currently investigating the effect of tranexamic acid in patients with spontaneous cerebral haemorrhage (patients who have not taken anticoagulants/NOAC).
In this study, we want to evaluate the effect of tranexamic acid in comparison to placebo in addition to standard medical treatment in a study at several centers.

Objectives:

Overall Objective
To demonstrate that treatment with TA for NOAC-ICH is beneficial. The results of this trial will determine whether TA should be used for the treatment of NOAC-ICH.

Primary Objective
The primary objective is to show that treatment with TA in patients with NOAC-ICH reduces the rate of HE as a surrogate marker for unfavourable outcome.

Secondary Objectives
Secondary objectives of this trial are to show that treatment with TA for NOAC-ICH increases the proportion of patients having a favourable clinical outcome and to show that TA influences hematoma expansion in different definitions.