Biomarkers and antithrombotic treatment in cervical artery dissection (TREAT-CAD)

Principal Investigator:	PD Dr. med. Georg Kägi
Status:	ongoing, recruitment finished
Project Start:	2015
Project End:	2019
Trial Design/Class:	national, multi-center /Class A-Clinical Trial
Number of Patients:	169 total (18 in St. Gallen)
Centers:	7 (Basel, Bern, Geneva – Main) (Lausanne, Zürich, Aarau, St. Gallen – Extension Study)
Sponsor/Partner:	Universitätsspital Basel/Prof. Dr. med. Stefan Engelter
Funding:	Universitätsspital Basel, Swiss National Science Foundation

Summary:

For the treatment of dissections, anticoagulant drugs (antithrombotic therapy) are used to counteract the formation of blood clots and their consequences such as vascular occlusion and circulatory disorders of the brain. Antithrombotic therapy however can increase blood vessel hemorrhage caused by vessel tearing and interfere with the occurrence of strokes through impairment of blood flow to the brain.
Basically, two different groups of antithrombotic therapies are available for the treatment of dissections:

• Acetylsalicylic Acid (Aspirin® oder Aspegic®)
• Coumarins (Marcoumar® oder Sintrom®)

Most patients with dissections are treated with coumarins.. There are no randomized studies, however, that assess the benefit / risk ratios of aspirin compared to coumarin drugs. The data are currently mixed: some results of non-randomized studies suggest superiority of acetylsalicylic acid and others of coumarins, and others show no difference. Furthermore, previous studies suggest that an inflammatory process in the arterial wall may be involved, in particular in the development of spontaneous dissections, by making the arterial wall "vulnerable". In light of this, it is unclear whether therapy with acetylsalicylic acid, which also has an anti-inflammatory effect, has an additional benefit in the drug therapy of dissections in comparison to coumarins which have no anti-inflammatory effect.

Objectives

Primary: to demonstrate the non-inferiority of treatment with ASA to anti- coagulant treatment with vitamin K antagonists in patients after a cervical artery dissection (CAD).
Secondary: to investigate whether the level of MMP9,the ratio of MMP9 to TIMP2 or other biomarker signatures will be associated with efficacy or safety measures stratified to the allocated treatment regimen.
TCD-sub-study: to (i) detect the frequency of MES in CAD-patients, (ii) evaluate the meaning of MES by addressing the following questions:
a) Is there an association of MES (presence or number) with the occurrence of clinical and/or surrogate MR outcome measures?
b) Is there an interaction between MES, type of treatment and outcome events?