MidregiOnal proatrial natriuretic peptide to guide Secondary Stroke prevention: The MOSES Study

Principal Investigator:	PD Dr. med. Georg Kägi
Status:	ongoing, recruiting
Project Start:	2020
Project End:	2023
Trial Design /Class:	International, multicenter, randomized-controlled, two-arm, assessor-blinded trial, Category: B
Number of Patient:	590 patients total (295 in each arm)
Centers:	six sites in Switzerland, 4 to 5 sites in European countries
Sponsor/Partner:	Universitätsspital Zürich / Universität Zürich
Funding:	Swiss National Science Foundation

Summary:

The present trial is addressing the question if a biologically distinct subgroup of ischemic stroke patients without known atrial fibrillation at admission, selected by a cut-off level of MRproANP concentration, which represents a underlying increased risk of cardiac thrombogenicity, benefits from direct oral anticoagulation (DOAC) versus antiplatelets as preventive treatment.
Three DOACs with marketing authorisation in Switzerland and the EU for the prevention of stroke and systemic embolism in patients with atrial fibrillation can be used. Eligible patients will be randomly assigned to either the control (antiplatelet) or the experimental (DOAC) arm with a ratio of 1:1. Each study participant will be observed during a follow up period within one year after index stroke.

Objectives:

Overall Objective
The overall objective of this study is to demonstrate that the efficacy of direct oral anticoagulants (DOACs) is superior to antiplatelet therapy for the prevention of stroke recurrence in MRproANP selected acute ischemic stroke patients without known AF on admission.

Primary Objective
The study seeks primarily to determine the effect of DOACs on reducing rates of recurrent stroke of any type compared to antiplatelet therapy within one year after index ischemic stroke in patients who have MRproANP levels > 200pmol/L and no known AF at randomization.

Secondary Objectives
The study seeks secondarily to determine the effect of DOACs on reducing rates of the composite of major bleeding, recurrent stroke of any type, and/or vascular death compared to antiplatelet therapy within one year after index ischemic stroke in MRproANP selected patients without known atrial fibrillation.

Safety Objectives
Bleeding rates compared between both treatment arms is the primary safety aspect in this trial and is part of the secondary outcome measure.