

Early versus Late initiation of direct oral Anticoagulants in post-ischaemic stroke patients with atrial fibrillation (ELAN): an international, multicentre, randomised-controlled, assessor-blinded trial

Principal Investigator:	Dr. med. Jochen Vehoff
Status:	ongoing, recruiting
Project Start:	2017
Project End:	2021
Trial Design /Class:	international, multicentre, randomised-controlled, two-arm assessor-blinded trial, Class: A
Number of Patient:	1802 total
Centers:	Switzerland (Aarau, Basel, Bern, Chur, Fribourg, Geneva, Lausanne, Lugano, Luzern, Nyon, Sion, St. Gallen, Zürich) Italy, Germany, Greece, Finland, UK, Austria, Norway, Portugal, approximately 80 sites
Sponsor/Partner:	Inselspital Bern / Prof. Dr. med. Urs Fischer, MD, MSc
Funding:	Inselspital Bern, Swiss National Science Foundation, Swiss Heart Foundation

Summary:

A stroke can be caused by atrial fibrillation (AF) an irregular heart rhythm. Patients with such a stroke are at higher risk of suffering further strokes. So far, we treat such patients with an anticoagulant. New medications have been on the market for a few years (direct oral anticoagulants), which, in comparison to older medication, reduce the number of new strokes and at the same time cause fewer cerebral haemorrhages. In all previous clinical trials, these new medications were used at the earliest one week after the first stroke. So far, there is no study that has investigated the safety of an earlier start of the treatment compared to a later time of treatment. However, recent studies show that early treatment with anticoagulants may lead to fewer strokes and less cerebral haemorrhages. This randomized international trial aims to estimate the net benefit of early initiation of DOACs as compared to late initiation of DOACs according the current standard practice in patients with acute ischaemic stroke and AF.

Objectives:

Overall Objective:

The ELAN trial aims to estimate the net benefit of early initiation of DOACs as compared to late initiation of DOACs according the current standard practice in patients with acute ischaemic stroke and AF.

Primary Objective

The main objective is to determine the net benefit of early versus late initiation of DOACs in patients with acute ischaemic stroke related to AF. Net benefit is estimated by a composite outcome that combines the outcomes of interest (recurrent ischaemic stroke and systemic embolism) to estimate efficacy and the bleeding outcomes of interest (intracerebral and extracranial major bleeding) as well as vascular death to estimate safety.

Secondary Objectives

The secondary objectives are to assess all vascular events and all-cause mortality after early initiation of DOACs in patients with acute ischaemic stroke related to AF compared to late initiation.