Oslo University Hospital

Protocol summary: *Study of Antithrombotic Treatment after Intracerebral Haemorrhage (STATICH)*

Background: Many patients with intracerebral haemorrhage have risk factors for ischaemic events and an indication for antithrombotic treatment (antiplatelet or anticoagulant agents). It is unknown whether patients with intracerebral haemorrhage and risk of ischaemic events should receive antithrombotic medication or not.

Study question:

1. In patients with spontaneous intracerebral haemorrhage, what is the effect of antithrombotic treatment on the risks of ischaemic events and new intracerebral haemorrhage?
2. What is the importance of microhaemorrhage on MRI for the effects of antithrombotic treatment?

Study design*:* Randomised-controlled, open study ("PROBE-design") of antithrombotic treatment after intracerebral haemorrhage: i) antiplatelet treatment vs. no antithrombotic treatment (for patients with indication for antiplatelet treatment), or ii) anticoagulant treatment vs. no anticoagulant treatment (for patients with atrial fibrillation).

Randomisation and treatment*:* Central randomisation (over the Internet) to i) antiplatelet treatment vs. no antithrombotic treatment (for patients with indication for antiplatelet treatment), or ii) anticoagulant treatment vs. no anticoagulant treatment (for patients with atrial fibrillation). The treatment duration will be 2 years.

Inclusion criteria (simplified): Adults with spontaneous (non-traumatic) intracerebral haemorrhage and with indication for antithrombotic treatment.

Radiological examinations: All patients will be examined with MRI (or CT) before randomisation. Patients who are examined with MRI will be invited to participate in a MRI sub-study with repeat MRI at 2 years.

Follow-up and effect variables*:* Follow-up every sixth months via telephone or letter from the co-ordinating centres in the Nordic countries. Follow-up via national registries and hospital records at 5 and 10 years. Primary endpoint: Symptomatic intracerebral haemorrhage. Secondary endpoints: Ischaemic events, other haemorrhage, and death.

Study size, centres and timeframe*:* 500 patients from centres in the Nordic countries. Start of pilot trial: June 2018. End of inclusion: June 2020. End of 2 years follow-up: June 2022.

Funding*:* South-Eastern Norway Regional Health Authority

Sponsor and trial co-ordinating centre: Oslo University Hospital (Oslo, Norway). Trial manager: Kristin Tveitan Larsen (k.t.larsen@medisin.uio.no). Trial co-ordinating investigator: Eivind Berge (eivind.berge@medisin.uio.no).

National co-ordinators: Eivind Berge (Norway), Eva-Lotta Glader (Sweden), Johanna Pennlert (Sweden), Christina R. Kruuse (Denmark).

EudraCT-number: 2014-002636-13.