APACHE-AF: Apixaban versus antiplatelet drugs or no antithrombotic treatment after anticoagulation-associated intracerebral haemorrhage in patients with atrial fibrillation. A randomised phase II clinical trial.

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Background

There is a lack of evidence on the optimal prevention of ischaemic stroke in patients with atrial fibrillation and a recent intracerebral haemorrhage (ICH) during treatment with oral anticoagulation. Patients are currently treated with:

- oral anticoagulants
- antiplatelet drugs, or
- no antithrombotic treatment.

Treatment with a direct oral anticoagulant like apixaban might be an attractive alternative in terms of a lower risk of recurrent ICH than with a vitamin-K antagonist, while at the same time being effective for the prevention of ischaemic stroke.

Objective

To obtain reliable estimates of the rates of vascular death or non-fatal stroke in patients with atrial fibrillation and a recent anticoagulation-associated ICH who are treated with apixaban versus those who are not treated with oral anticoagulation.

Study design

Multi-centre, phase II, randomised, open-label clinical trial with blinded outcome assessment.

Study population

100 adults with a history of atrial fibrillation and a recent intracerebral haemorrhage during treatment with oral anticoagulation in whom clinical equipoise exists on the optimal stroke prevention therapy.

Fig. 1 | Trial flowchart

Trial status (May 2018)

16 sites recruiting the Netherlands

Fig. 2 | Participating sites

46 patients randomized, with a mean age of 77.5 years (SD 7.5 years), 25 males (54%)

17 patients with lobar and 29 with non-lobar ICH

66.4 patient-years of follow-up

Intervention

Patients will be randomised between 7 and 90 days after the index haemorrhage to

- 1) apixaban 5mg twice daily or
- 2) any antiplatelet drug or no antithrombotic treatment, at the discretion of the treating physician.

Primary outcome measure

Vascular death or non-fatal stroke during follow-up.

Sample size

Ten primary outcome events in 100 patient-years of follow-up will yield a 95% confidence interval of 4.9 to 17.6.

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