

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

Patients with atrial fibrillation and a recent intracerebral haemorrhage (ICH) during treatment with oral anticoagulation 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 low risk of recurrent ICH, 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 treated with apixaban versus those who are treated with antiplatelet drugs or no antithrombotic drug at all.

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



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Intervention

Patients will be randomised to

- 1) apixaban 5 mg twice daily or
- 2) antiplatelet drugs antithrombotic treatment, at the discretion of the treating physician.

Patients will be randomized between 7 and 90 days after the index haemorrhage.

Primary outcome measure

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

Trial status

Status: recruiting in 10 sites, 4 patients randomised.

Principal investigators

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Fig. 2 | Participating sites

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