

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 marked 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. These patients are currently treated with oral anticoagulants, antiplatelet drugs, or no antithrombotic treatment, depending on personal and institutional preferences. 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 with atrial fibrillation and a recent anticoagulation-associated intracerebral haemorrhage who are 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.

Intervention

Patients will be randomised to 1) apixaban 5 mg twice daily or 2) any antiplatelet drug or no 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.

Sample size

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

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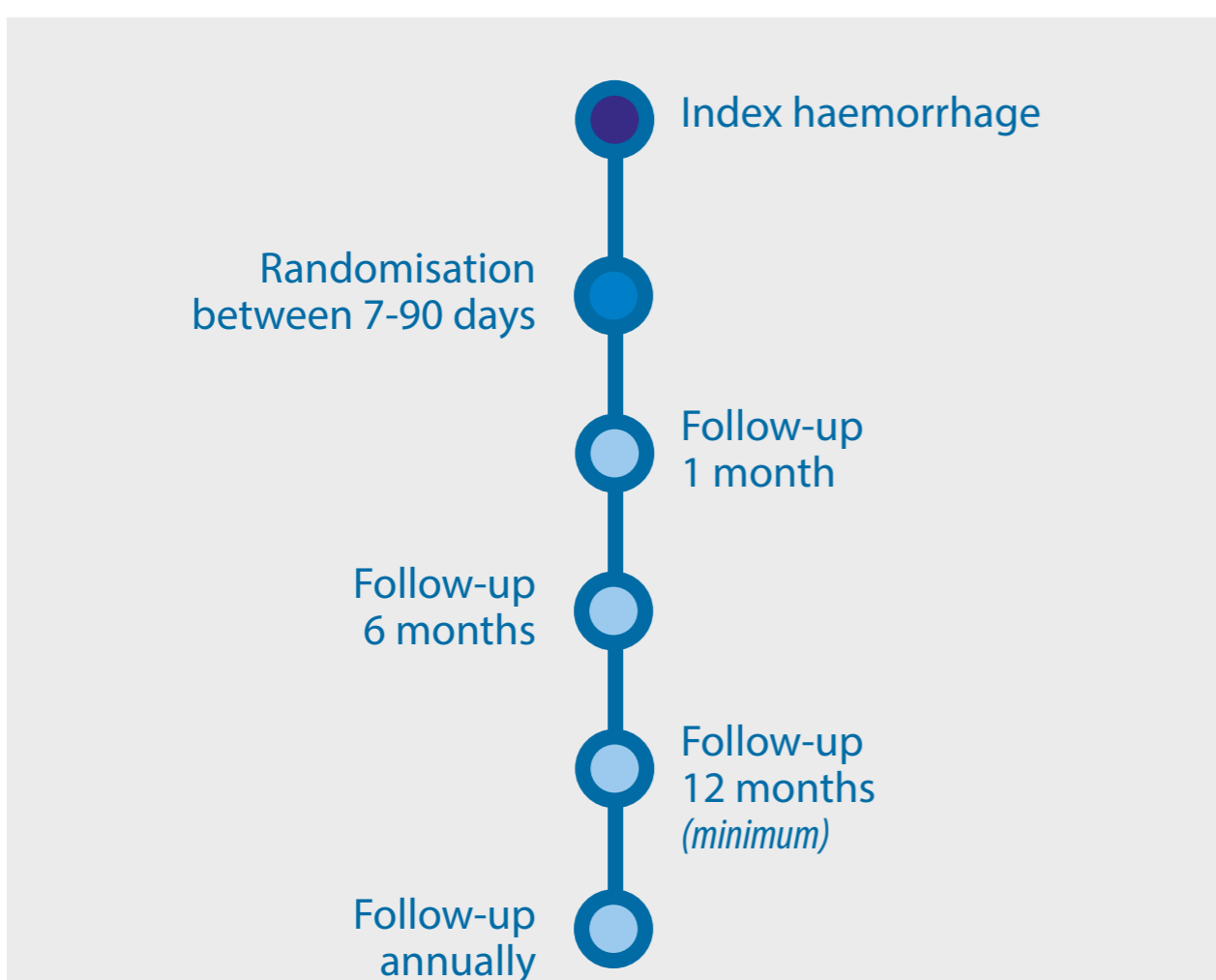


Fig. 1 | Trial flowchart