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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.

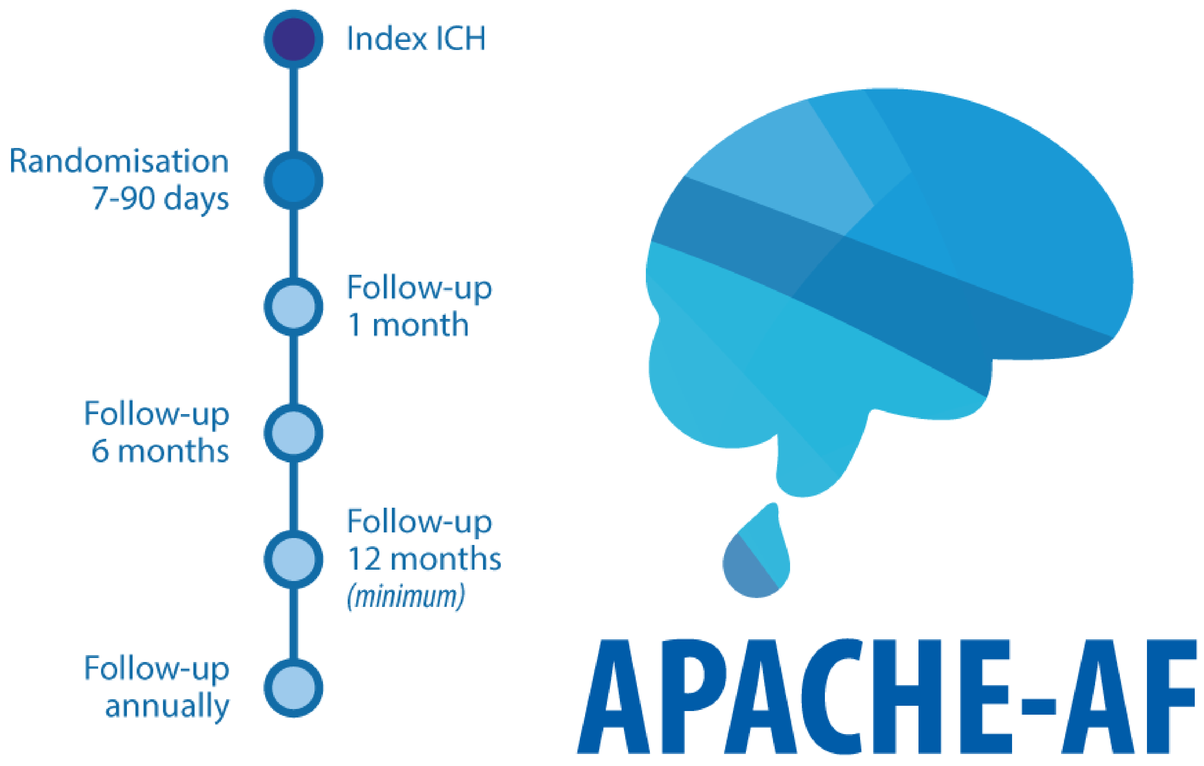

Fig. 1 | Trial flowchart

Trial status (May 2018)

16 sites recruiting the Netherlands

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

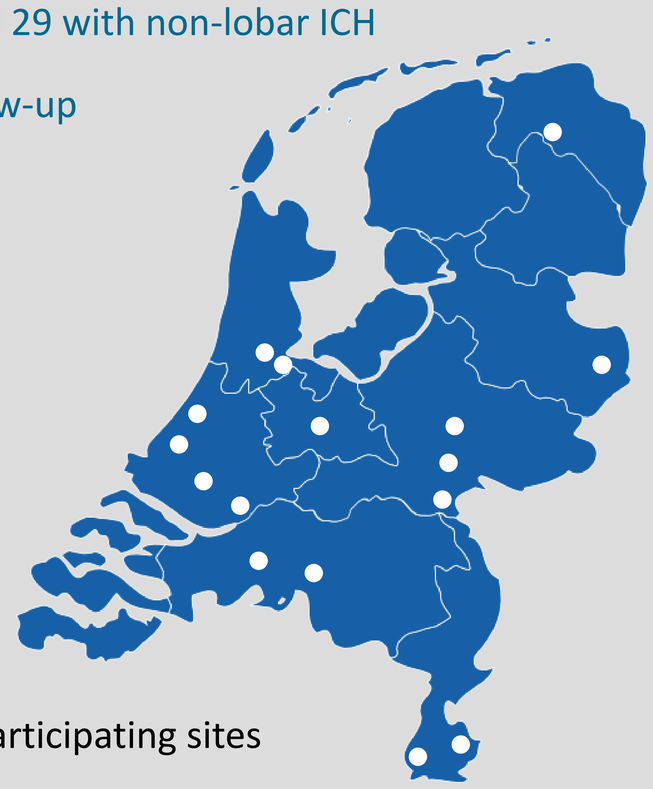

Fig. 2 | Participating sites

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

Non-fatal stroke or vascular death 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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