Blood thinners (anticoagulants) cause bleeding without preventing stroke in patients with atrial high-rate episodes (AHRE), but without electrocardiogram (ECG)-diagnosed atrial fibrillation. The results clearly suggest to demand ECG documentation of atrial fibrillation prior to initiation of oral anticoagulation.

NOAH-AFNET 6 was the first trial to investigate the efficacy and safety of oral anticoagulation in patients with AHRE, but without ECG-documented atrial fibrillation.

**Study objectives**

NOAH-AFNET 6 trial
Oral anticoagulation in patients with atrial high-rate episodes

**Study population**

Patients ≥ 65 years with

- AHRE episodes ≥ 6 minutes detected by implantable devices
- ≥ 1 additional stroke risk factor
  - heart failure
  - hypertension
  - diabetes
  - prior stroke or transient ischaemic attack
  - vascular disease
  - age ≥ 75 years

**Who and what?**

2,536* patients

randomised 1:1

anticoagulation (edoxaban)

no anticoagulation (placebo with no active compound or aspirin 100 mg once daily in patients with an indication for antiplatelet therapy)

*the primary, modified intention-to-treat analysis population who received ≥ 1 dose of study drug

The trial was stopped early due to safety signals and a trend towards futility for efficacy after enrolment of all planned patients.

**Where?**

18 European countries

206 sites

**Primary endpoint**

Composite of stroke, systemic embolism, or cardiovascular death

Rate% 3.2%/year vs. 4.0%/year

Hazard ratio 0.81
95% CI 0.6–1.1; p=0.15

**Safety outcome**

Composite of major bleeding and all-cause death

Rate% 5.9%/year vs. 4.5%/year

Hazard ratio 1.3
95% CI 1.0–1.7; p=0.03

The difference in safety outcomes was driven by an expected increase in major bleeding with

Hazard ratio 2.10
95% CI 1.30–3.38; p=0.002