Facts

International Chief Investigator
Paulus Kirchhof, MD

Number of Patients
3.400

Participating Countries and National Coordinators

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Germany:	Christopher Piorkowski, MD
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Netherlands:	Joris de Groot, MD
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Sponsor
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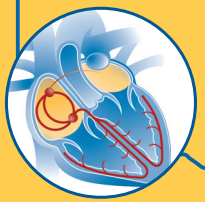

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Non-vitamin K antagonist Oral anticoagulants in patients with Atrial High rate episodes

AFNET 6
N O A H

NOAH – AFNET 6 Trial

Non-vitamin K antagonist **O**ral anticoagulants in patients with **A**trial **H**igh rate episodes (NOAH)

Registration
EudraCT number: 2015-003997-33
ClinicalTrials.gov: NCT02618577
ISRCTN: ISRCTN17309850

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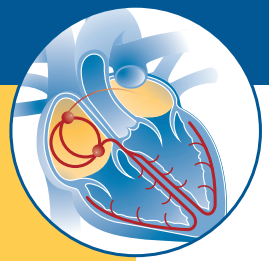

NOAH – AFNET 6 Trial

NOAH – AFNET 6 is an investigator initiated, prospective, parallel-group, randomized, double-blind, multi-center trial to evaluate the potential benefit of oral anticoagulation therapy in patients with atrial high rate episodes (AHRE), but without overt atrial fibrillation (AF).

AF is a common cause of stroke. Patients suffering from AF, if documented by an ECG, benefit from oral anticoagulation treatment with vitamin K antagonists (VKAs) or non-vitamin K antagonist oral anticoagulants (NOACs), thus preventing strokes. However, a large proportion of AF episodes remain undiagnosed ("silent AF"), and many patients present with a stroke as the first clinical sign of AF. Earlier initiation of anticoagulation could prevent such events.

Continuous monitoring of atrial rhythm by implanted devices could close this diagnostic gap. Modern pacemakers and defibrillators provide automated algorithms alerting to the occurrence of AHRE. There is evidence that stroke rate is increased in patients with AHRE, and some patients develop AF after initially presenting with AHRE. In these patients, AHRE can be considered as an early manifestation of AF. On the other hand, anticoagulation therapy creates a risk for major bleeding complications.

Hence, there is uncertainty about the optimal antithrombotic therapy in patients with AHRE. NOAH will test, whether treatment with the newly introduced NOAC edoxaban is superior to current therapy to prevent stroke, systemic embolism, or cardiovascular death in this patient group.

The pan-European trial plans to enroll more than 3.000 patients in 200 to 250 study centres in more than 15 European countries with adequate experience in the follow-up of implanted pacemakers or defibrillators in clinical routine. The study participants will be randomized to either receiving edoxaban or receiving the best current care consisting of antiplatelet therapy or no therapy depending on the cardiovascular risk.

The NOAH trial was started in June 2016.
As a physician you may – if qualified accordingly – participate in the NOAH trial by enrolling patients. Patients are eligible for NOAH, if they meet the following criteria:

- Pacemaker or defibrillator implanted for any reason with feature of detection of AHRE, implanted at least 2 months prior to randomization
- AHRE (≥ 180 bpm atrial rate and ≥ 6 min duration) documented by the implanted device via its atrial lead and stored digitally
- Age ≥ 65 years
- In addition, at least one stroke risk factor leading to a CHA_2DS_2VASc score of 2 or more.

Patients with overt AF are not eligible.

About AFNET

The Atrial Fibrillation NETwork (AFNET) is an interdisciplinary research network comprising scientists and physicians from hospitals and practices dedicated to improving the management of atrial fibrillation through coordinated research in Germany, Europe, and the USA. Its main objective is to conduct high quality investigator-initiated clinical trials and registries on a national and international level. The AFNET continues the long-term activities of the network which has been funded by the German Federal Ministry of Research and Education for over a decade. Since January 2015, specific projects and infrastructures of the AFNET are funded by the German Centre for Cardiovascular Research (DZHK).

NOAH Partners

DZHK
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