Facts

Coordinating Investigators
Paulus Kirchhof, MD
(International Chief Investigator)
Luigi di Biase, MD
(International Co-Chief Investigator)

Number of Patients
630

Participating Countries and National Coordinators

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Germany:	Gerhard Hindricks, MD
Great Britain:	Joseph De Bono, MD
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Netherlands	Isabelle van Gelder, MD
Spain:	Lluis Mont, MD
USA:	Luigi di Biase, MD

Sponsor
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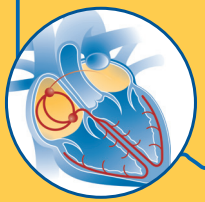

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Anticoagulation using the direct factor Xa inhibitor apixaban during Atrial Fibrillation catheter Ablation: Comparison to vitamin K antagonist therapy

AFNET 5
A X A F A

AXAFA – AFNET 5 Trial

Anticoagulation using the direct factor **X**a inhibitor apixaban during **A**trial **F**ibrillation catheter **A**blation: Comparison to vitamin K antagonist therapy (AXAFA)

Registration
EudraCT number: 2014-002442-45
ClinicalTrials.gov: NCT02227550
ISRCTN: ISRCTN87711003

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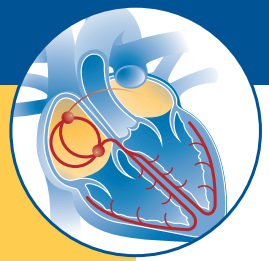

AXAFA – AFNET 5 TRIAL

AXAFA – AFNET 5 is an investigator-driven, prospective, parallel-group, randomised, open, blinded outcome assessment (PROBE), multi-centre trial to determine the optimal anticoagulation therapy for patients undergoing catheter ablation of atrial fibrillation.

5-15 % of the patients suffering from AF undergo catheter ablation treatment. During and after the ablation procedure they require anticoagulation to reduce the risk of procedure-associated stroke. Factor Xa inhibitors and direct thrombin inhibitors are new oral anticoagulants (NOACs) that provide an alternative treatment to vitamin K antagonists (VKAs) for stroke prevention in AF. Their use has been evaluated in several large clinical trials. So far, it has not been examined whether NOACs can be used in the setting of catheter ablation of AF.

AXAFA is to test whether anticoagulation with the direct factor Xa inhibitor Apixaban is as safe as VKA therapy in patients undergoing catheter ablation of AF in the prevention of peri-procedural complications such as death, stroke, and major bleeding events. The prospective, parallel-group, randomized, open, blinded outcome assessment, multi-center trial will enroll 630 AF patients who will undergo catheter ablation. About 50 study centers – 25 in Europe and 25 in the USA – that routinely perform catheter ablation will enroll the patients after obtaining informed consent.

The study participants will be randomized to either receive the factor Xa inhibitor Apixaban or VKA therapy. They will have to take the medicine for at least 30 days prior to the planned catheter ablation procedure. This interval may be shorter in patients undergoing a transesophageal echocardiogram (TEE) with exclusion of atrial thrombi. In this case the ablation can be performed shortly after the first taking of the medicine. Study medication has to be continued for three months after the ablation procedure. All patients will be treated following the current guidelines.

The AXAFA trial was started in February 2015.
As a physician you may – if qualified accordingly – participate in the AXAFA trial by enrolling patients. Patients are eligible for AXAFA, if they meet the following criteria:

1. Non-valvular AF (ECG-documented) with a clinical indication for catheter ablation
2. Clinical indication to undergo catheter ablation on continuous anticoagulant therapy
3. Presence of at least one of the CHADS2 stroke risk factors
   - Stroke or TIA
   - Age ≥ 75 years
   - Hypertension
   - Diabetes mellitus
   - Symptomatic heart failure (NYHA ≥ II).
4. Age ≥ 18 years

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 over a decade. Since January 2015, specific projects and infrastructures of the AFNET are funded by the German Centre for Cardiovascular Research (DZHK).

AXAFA Partners

DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

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