Trial Description

Title

APAF Apixaban in Atrial Fibrillation Registry

Trial Acronym

APAF

URL of the trial

[---]*

Brief Summary in Lay Language

Objective of the registry is to assess the use of antithrombotic therapies and adherence to guidelines in patients with non-valvular atrial fibrillation.

Brief Summary in Scientific Language

Atrial fibrillation (AF) confers a substantial risk of mortality and morbidity from stroke and thromboembolism, and this common cardiac arrhythmia represents a major healthcare burden in Europe. Stroke prevention is central to the management of AF patients, with oral anticoagulation (OAC) using well-controlled adjusted dose vitamin K antagonists or novel OACs being recommended for patients with AF with ≥1 stroke risk factors. Also, the 2012 focused update of the ESC guidelines strongly advocates a clinical practice shift so that the initial decision step now is the identification of 'truly low risk' patients, essentially those age<65 without any stroke risk factors (both male and female), who do not need any antithrombotic therapy. The ESC guidelines only recommend use of the CHA2DS2-VASc score for stroke risk assessment, and the 'low risk' patients are defined as those with a CHA2DS2-VASc score=0 (males) or score=1 (females). Subsequent to this initial step of identifying the low risk patients, effective stroke prevention (which is essentially OAC) can then be offered to AF patients with ≥1 stroke risk factors, with treatment decisions made in consultation with patients and incorporating their preferences. Despite these recommendations, a substantial number of patients with AF is not treated with OAC. On the

other hand, patients with AF and low risk are being "overtreated", receiving OAC despite a CHADS-VASc score of 0. Therefore, this registry will determine, if patients with non-valvular AF are treated ac-cording to current guidelines.

Apixaban is an oral factor Xa inhibitor, which has been tested in a number of indications. In the AVERROES study in patients with non-valvular atrial fibrillation deemed not suitable for treatment with a vitamin-K antagonist apixaban compared to aspirin reduced the incidence of stroke and systemic embolism without increasing bleeding complications. In the large ARISTOTELE study apixaban was superior to warfarin, it re-duced the primary endpoint of stroke and systemic embolism caused less bleeding and reduced all-cause mortality. Subsequently apixaban has been approved by the European health authorities for the use in patients with atrial fibrillation. It is therefore of interest to determine use of apixaban in real life with respect to patient selection, adherence to therapy and midterm efficacy and safety.

Organizational Data

- DRKS-ID: **DRKS00011080**
- Date of Registration in DRKS: **2016/09/21**
- Date of Registration in Partner Registry or other Primary Registry: **2015/09/21**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **837.279.15 (10047) , Ethik-Kommission bei der Landesärztekammer Rheinland-Pfalz**

Secondary IDs

- Primary Registry-ID: **NCT02563639 (ClinicalTrials.gov)**
- Sponsor-ID: **CV185-404 (IHF GmbH - Institut für Herzinfarktforschung)**

Health condition or Problem studied

- Free text: **Atrial Fibrillation**
- ICD10: **I48.0 - [generalization I48: Atrial fibrillation and flutter]**

Interventions/Observational Groups

- Arm 1: **Patients with atrial fibtrillation (new diagnosed, paroxysmal, permanent or persistent), 5000 patients, consecutive enrollment in the registry, oberservational period 12 months**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- Comparison of antithrombotic therapy for atrial fibrillation: Prescribed drugs; time frame: 12 months; Name of antithrombotic drug

Secondary Outcome

- Safety of Apixaban as assessed by MACCE, Haemorrhagic complications, Ischemic clinical events, Stroke, Systemic embolism, Hospitalisations for stroke, cardiac reasons or bleeding complications; time frame: 12 months; MACCE (death / MI / stroke)
Haemorrhagic complications (major / minor bleeding)
Ischemic clinical events (non-fatal MI, cardiac death, etc.)
Stroke (ischemic, haemorrhagic)
Systemic embolism
Hospitalisations for stroke, cardiac reasons or bleeding complications
- Quality of Life; time frame: 12 months; Questionnaire (EQ-5D-5L)
- Comparison of antithrombotic therapy for atrial fibrillation: Dose of drugs; time frame: 12 months; Dose of antithrombotic drug
- Comparison of antithrombotic therapy for atrial fibrillation: Duration of treatment; time frame: 12 months; Duration of treatment [months]
- Comparison of antithrombotic therapy for atrial fibrillation: Contraindications for anticoagulation; time frame: 12 months; Relative and absolute contraindications to anticoagulation at baseline and history
- Comparison of antithrombotic therapy for atrial fibrillation:Selection of anticoagulant; time frame: 12 months; Basis for the selection of the anticoagulant

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinikum Ludwigshafen, Ludwigshafen**
- Medical Center **Klinikum Konstanz, Konstanz**
- Medical Center **Carl-von-Basedwo Klinikum, Merseburg**
- Medical Center **Krankenhaus Buchholz, Buchholz**
- Medical Center **Klinikum Worms, Worms**
- University Medical Center **Lübeck**
- Medical Center **Siegen**
- Medical Center **Wittstock**
- Medical Center **Euregio Klinik Nordhorn**
- Medical Center **Elblandklinikum, Riesa**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/09/30**
- Target Sample Size: **5000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Age ≥18 years
- Non-valvular atrial fibrillation
- In hospitals or specialized or non-specialised office-based centres
- Written informed consent for participation in observational study (incl. telephone follow-ups)

- **Not simultaneously participating in any randomized trial**

Exclusion criteria

No exclusion criteria

Addresses

■ **Primary Sponsor**

IHF GmbH - Institut für Herzinfarktforschung
Bremserstraße 79
67063 Ludwigshafen
Germany

Telephone: **0621 503 2814**
Fax: **[---]***
E-mail: **frey at ihf.de**
URL: **[---]***

■ **Contact for Scientific Queries**

Klinikum Ludwigshafen
Mr. Prof. Dr. Uwe Zeymer
Bremserstraße 79
67063 Ludwigshafen
Germany

Telephone: **0621 503 0**
Fax: **[---]***
E-mail: **frey at ihf.de**
URL: **[---]***

■ **Contact for Public Queries**

IHF GmbH
Mr. Erich König
Bremserstraße 79
67063 Ludwigshafen
Germany

Telephone: **+49 621 595 77 218**
Fax: **+49 621 595 77 400**
E-mail: **koenig at ihf.de**
URL: **www.ihf.de**

Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

  IHF GmbH
  Bremserstraße 79
  67063 Ludwigshafen
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/08/15**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*