Factor XA - Inhibition in RENal Patients With Non-valvular Atrial Fibrillation - Observational Registry (XARENO-Registry)

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Study Finalised

Administrative details

EU PAS number

EUPAS32349

Study ID

37091

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- France
- Germany

Switzerland

Study description

This is a prospective registry allowing a structured, non-interventional collection of data. Participating physicians will not be subject to any instructions with regard to the diagnosis and therapy of their patients. All patient treatment is carried out within clinical routine, at the discretion of the physician and according to existing treatment guidelines. This registry will be carried out as an investigator-initiated, multicentre, prospective, non-interventional and observational registry at approximately 200 sites in Germany, Austria, Switzerland, France, Belgium and Luxembourg. The registry will collect clinical data of approximately 2500 patients with CKD (eGFR 15-49 mL/min per 1.73 m2) and NVAF receiving rivaroxaban, OAC with VKA, or no AC therapy, who are prospectively followed for a flexible duration with at least for 12 months (for the last enrolled patient) and with an estimated mean of 18 months for the whole study cohort. It is planned to include 1000 patients with rivaroxaban therapy and VKA therapy, respectively. Enrolment can be prolonged beyond 2500 patients until 1000 rivaroxaban patients are enrolled.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 160 centres are involved in the study

Contact details

Study institution contact

Reinhold Kreutz reinhold.kreutz@charite.de

Study contact

reinhold.kreutz@charite.de

Primary lead investigator

Reinhold Kreutz

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/12/2015

Actual: 15/12/2015

Study start date

Planned: 01/02/2016

Actual: 25/04/2016

Date of final study report

Actual: 06/01/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

XARENO Protocol_V2.0_final_SIGNED.pdf (1.2 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

NCT02663076 - Clinicaltrials

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The multicentre registry will collect clinical data from 2500 patients with NVAF and chronic kidney disease (CKD) with an estimated glomerular filtration rate (eGFR) (15-49 mL/min per 1.73 m2). The overall objective of this registry is to assess CKD progression and safety of anticoagulation strategies in NVAF patients with eGFR 15-49 mL/min per 1.73 m2 in routine clinical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multicentre, prospective, and observational registry

Study drug and medical condition

Medical condition to be studied

Chronic kidney disease

Additional medical condition(s)

Non-valvular Atrial Fibrillation (NVAF)

Population studied

Short description of the study population

Patients with non-valvular atrial fibrillation (NVAF) and chronic kidney disease (CKD) aged 18 years or older received treatment with rivaroxaban therapy or VKA therapy or no anticoagulation therapy.

Inclusion criteria:

- Male and female patients, age ≥ 18 years
- CKD with eGFR 15 – 49 mL/min per 1.73 m2
- Documented NVAF with indication for anticoagulation therapy
- A treatment strategy for the ≥ 3 previous months before enrolment with either:

■ rivaroxaban or

■ VKA (oral anticoagulation [OAC] cohorts) or

■ no anticoagulation (no AC cohort) received (if applicable) at the earliest in January 2012

- Informed consent
- Availability for follow-up
- Life expectancy of ≥ 6 months

Exclusion criteria:

- Exclusion criteria according to the local product information for the respective

anticoagulation treatment

- Planned chronic treatment with other anticoagulants

- Expected renal replacement therapy within the next 3 months

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Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with atrial fibrillation and chronic kidney disease

Estimated number of subjects

1.600

Study design details

Outcomes

- decline in eGFR in mL/min per 1.73 m2 - major bleeding - all-cause mortality - TIA, stroke or systemic arterial embolism - major cardiovascular events (MACE) - Myocardial infarction - Acute coronary syndrome/unstable angina - symptomatic venous thromboembolic events - net-clinical benefit (stroke and other thromboembolic events, major bleeding, and all-cause mortality), - initiation of chronic renal replacement therapy - eGFR < 15 mL/min per 1.73 m2

(CKD Stage 5 Dialysis and Non-Dialysis) - eGFR decline of ? 30% - doubling of serum creatine concentration - acute kidney injury (AKI) events - rates, causes and length of hospitalizations - persistence with OAC therapy - reasons for OAC therapy discontinuation

Data analysis plan

Statistical analyses will be descriptive and exploratory only. For continuous parameters summary statistics will be presented. For categorical variables absolute and relative frequencies will be presented. All tables will be generated by treatment (Rivaroxaban, VKA or no AC) and total. To get an idea if potentially observed differences in treatment could be of relevance, 95 % confidence intervals of the treatment differences between Rivaroxaban and VKA will be calculated.

Documents

Study results

XARENO CSR V1.0_2023-01-06_Synopsis.pdf (102.61 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No