Adverse ReNal OuTcomEs in patients with NoN-Valvular Atrial fibrillation treated with Rivaroxaban or Vitamin K Antagonists (ANTENNA)

First published: 05/03/2020

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS33537

Study ID

41352

DARWIN EU® study

No

Study countries

United Kingdom

Study description

By evaluating routine clinical practice data from the UK primary care database, researchers in this study want to gather information on the kidney function of patients with non-valvular atrial fibrillation (NVAF, irregularly heart beats which is not caused by a heart valve problem) who are treated with Rivaroxaban (non-vitamin K antagonist, brand name Xarelto) or vitamin K antagonists (VKAs). The study planned to enroll about 25,000 male or female patients who were at least 18 years old and were new users of Rivaroxaban or VKAs between 01 January 2014 and 30 September 2019. Researchers are especially interested in whether patients experienced under treatment any worsening in kidney function, the onset of acute kidney diseases or injuries. In addition, risk of worsening in kidney function in patients with or without diabetes or heart failures are of interest to the researchers

Study status

Finalised

Research institutions and networks

Institutions

Fundación Centro Español de Investigación Farmacoepidemiológica (CEIFE)

Spain

First published: 15/03/2010

Last updated: 15/02/2024

Institution **Not-for-profit** **ENCePP partner**

Contact details

Study institution contact

Bayer Clinical Trials BAYER AG clinical-trials-contact@bayer.com

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/02/2020

Actual: 02/02/2020

Study start date

Planned: 01/05/2020

Actual: 01/05/2020

Date of final study report

Planned: 30/04/2021

Actual: 27/04/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

Study 21347_Study protocol_Version 1_02Feb2020.pdf (1.51 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Evaluation of posisble difference in renal function decline under rivaroxaban and warfarin chronic treatment

Data collection methods:

Secondary use of data

Main study objective:

To estimate the magnitude of renal decline, incidence of end-stage renal disease (ESRD) and acute kidney injury (AKI) in patients with NVAF treated with rivaroxaban and those treated with a VKA according to the presence of CKD and its severity at the start of OAC therapy in UK primary care

Study Design

Non-interventional study design

Case-control

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

RIVAROXABAN

Anatomical Therapeutic Chemical (ATC) code

(B01AA03) warfarin

warfarin

Additional medical condition(s)

Non-Valvular Atrial fibrillation

Population studied

Short description of the study population

Patients with NVAF newly initiated on OAC therapy with either rivaroxaban or a VKA.

Inclusion criteria

• aged ≥18 years in the IMRD-UK database

• a first prescription for either rivaroxaban or a VKA between 01 January 2014 and 31 March 2019. The date of the first rivaroxaban/VKA prescription will be set as the start date (start of follow-up for that patient). The follow-up will be extended until 30 September 2019 to ensure that each patient has at least 6 months of
potential follow-up.

• A diagnosis of AF recorded any time before start date or within 2 weeks after start date.

• Registered with their general practice at least 1 year before the start date and have a recorded prescription of any drug at least 1 year before the start date.

• Registered with a general practice with data considered to be up-to-standard quality.

Exclusion criteria

• A prescription for any OAC before the start date – all first-time rivaroxaban/VKA users will therefore be OAC naïve
• A record of heart valve replacement or mitral stenosis any time before the start date or in the 2 weeks after the start date.
• A record of deep vein thrombosis, pulmonary embolism, or hip/knee surgery in the 3 months before the start date (because these are all alternative reasons for NOAC initiation
• A record of ESRD (including renal transplant patients) on/before the start date

---

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

Atrial fibrillation patients

Estimated number of subjects

25.000

Study design details

Outcomes

- %change in serum creatinine - doubling of serum creatinine - rate of eGFR change - %eGFR change - incidence of ESRD and AKI

Data analysis plan

Cohort analyses: The difference in the eGFR slopes after initiation between patients starting on rivaroxaban and on a VKA will be assessed using a linear mixed regression model. Only individuals with at least two recorded eGFR measurements after treatment initiation will be included in this analysis. Incidence rates of each adverse renal outcome will be calculated with 95% CIs assuming a Poisson distribution. Incidence rates will be stratified by age-group, sex, CKD stage at baseline, the starting OAC, and for rivaroxaban, the dose of the starting prescription (20 mg/day or 15 mg/day). A survival analysis using Cox proportional hazard regression, will be performed to compare the time to the occurrence of the study outcomes according to the starting OAC.
Case–control analyses: Unconditional logistic regression will be used to ORs with 95% CIs to estimate the associations between current exposure to rivaroxaban/VKA and and the study outcomes adjusted for confounders

Documents

Study results

21347_EU PAS Abstract_redacted_V1.0_2021-04-27.pdf (303.9 KB)

Study report

21347_Study Report_redacted_V1.0_2021-04-27.pdf (1.14 MB)

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

THIN

Data sources (types)

Electronic healthcare records (EHR)

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