Voluntary PASS non interventional study: Retrospective Observational Study of VKA and Novel Oral Anticoagulants in Patients with Non-valvular Atrial Fibrillation:

First published: 21/12/2015

Last updated: 31/01/2017

Study Planned

Administrative details

EU PAS number

EUPAS11897

Study ID

17533

DARWIN EU® study

No

Study countries

Japan

Study description

The four novel oral anticoagulants (NOACs) were available in Japan for reduction of the risk of stroke and systemic embolism (SE) among patients with NVAF: edoxaban in September 2014, apixaban in Februray, 2013, rivaroxaban in April 2012, and dabigatran etexilate in March 2011.Despite the evidence on efficacy and safety of these NOACs from RCTs, little is known about how they perform in real-world clinical practice settings. This study will assess the following- baseline demographics and clinical characteristics of NVAF patients prescribed apixaban, rivaroxaban, dabigatran or warfarin, treatment patterns of anitcoagulanttherapy, rates of occurrence of a bleeding event, and healthcare resource use. Edoxaban is excluded from this study because of limited sample size.

Study status

Planned

Research institutions and networks

Institutions

Crecon

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ruslan Horblyuk

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/10/2015

Study start date
Planned: 23/12/2015

Date of final study report
Planned: 30/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer-Japan

Study protocol

20151210_Pfizer-OAC_MDV_data_Japan_Protocol For REVIEW (2).pdf (427.95 KB)

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 type:

Non-interventional study

Scope of the study:

Other

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

Observational cohort Study

Main study objective:

To Compare the incidence of major bleeding events among NVAF patients newly initiated with apixaban versus each other OACs for 1 year after initiation of each OAC.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

A retrospective observational cohort study of NVAF patients treated for the prevention of stroke with OACs after NVAF diagnosis using large insurance claims data.

Study drug and medical condition

Medicinal product name

ELIQUIS

Medical condition to be studied

Atrial fibrillation

Population studied

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)

Estimated number of subjects

30.000

Study design details

Outcomes

Incidence of major bleeding will be compared between apixaban and warfarin. Incidence of and time to any bleeding among NVAF patients treated with apixaban, which are compared with other NOACs or warfarin.A rate of discontinuation and time to discontinuation of each OAC.Health-care resource utilization.

Data analysis plan

Baseline patient demographics information and healthcare resource utilization will be compared among the apixaban, rivaroxaban, dabigatran and warfarin cohorts by using chi-square test(categorical variables) and ANOVA with a post-hoc test (numerous variables). COX proportional hazard regression analysis will be used to compare the incidence of post treatment major bleeding among four OAC groups. Discontinuation of or switching from an index OAC will be compared among four OACs by using COX proportional hazard regression analysis.

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)

Administrative healthcare records (e.g., claims)

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