Thromboembolic and Bleeding Risks of Apixaban, Rivaroxaban and Dabigatran versus Warfarin in Patients with Non-Valvular Atrial Fibrillation

First published: 14/06/2018

Last updated: 02/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS24422

Study ID

29728

DARWIN EU® study

No

Study countries

☐ Taiwan

Study description

Oral anticoagulants (OACs) have proven to reduce the mortality and morbidity of thromboembolic events among patients with non-valvular atrial fibrillation (NVAF). Due to the recent market entrance of NOACs, few real-world clinical studies have evaluated the treatment patterns among NVAF patients prescribed warfarin and NOACs.The main goal of this study is to compare the risk of major bleeding, and risk of stroke, including hemorrhagic and ischemic stroke, and systemic embolism (SE) among Asian NVAF patients newly initiated with warfarin versus each of the NOACs (i.e., apixaban, dabigatran, rivaroxaban) in the real-world setting. Edoxaban was reimbursed in September 2016, limited patients are expected to be available hence the drug was excluded.

Study status

Planned

Research institutions and networks

Institutions

Taipei Veterans General Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Tze-Fan Chao

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/03/2018

Actual: 20/04/2018

Study start date

Planned: 30/06/2018

Date of final study report

Planned: 31/07/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Limited

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:

Effectiveness study (incl. comparative)

Main study objective:

Compare the safety and effectiveness for OAC treatment naïve patients prescribed dabigatran, rivaroxaban and apixaban or warfarin

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Longitudinal retrospective cohort analysis

Study drug and medical condition

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

WARFARIN

APIXABAN

DABIGATRAN

RIVAROXABAN

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

80000

Study design details

Outcomes

Several important effectiveness and safety endpoint will be analyzed, including stroke/ SE, major bleedings, mortality, ischemic stroke, systemic embolism, acute myocardial infarction, intracranial hemorrhage, GI bleeding and GU tract bleeding.

Data analysis plan

All study variables, including baseline and outcome measures, will be analyzed descriptively. Percentages and standard deviations will be provided for dichotomous and polychotomous variables. Means, medians and standard deviations will be provided for continuous variables. The study cohorts will be compared for baseline clinical and demographic variables according to the objectives. Propensity Score Matching technique will be used to control for confounders when comparing the cohorts. Cox proportional hazards models will be used to compare the time-to-major bleeding, time-to-stroke, time-to-discontinuation, and time-to-switch between the apixaban, warfarin, rivaroxaban, and dabigatran cohorts.

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