The Comparative Safety and Effectiveness of Warfarin and Dabigatran Utilized in the Department of Defense (DoD) Non-Valvular Atrial Fibrillation (NVAF) Patient Population- A Retrospective Database Analysis

First published: 20/05/2015

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Study Ongoing

Administrative details

EU PAS number

EUPAS9771

Study ID

9772

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study is of a retrospective cohort design with propensity score matching. The primary study objective is to assess the safety and effectiveness of dabigatran compared to warfarin in patients diagnosed with non-valvular atrial fibrillation in the DoD population.

Study status

Ongoing

Research institutions and networks

Institutions

Evidera

United Kingdom

First published: 20/11/2013

Last updated: 07/03/2024

Institution | **Laboratory/Research/Testing facility** | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Evidera Evidera

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 27/09/2013

Actual: 27/09/2013

Study start date

Planned: 22/01/2014

Actual: 22/01/2014

Data analysis start date

Planned: 04/07/2014

Actual: 23/05/2014

Date of final study report

Planned: 15/06/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Pharmaceuticals, Inc.

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To assess the safety and effectiveness of dabigatran and warfarin in patients diagnosed with non-valvular atrial fibrillation in the DoD population.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

PRADAXA

Name of medicine, other

Warfarin

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

28000

Study design details

Outcomes

stroke (hemorrhagic, ischemic), major bleeding, Ischemic stroke, Hemorrhagic stroke, Major Intracranial bleeding, Major Extracranial bleeding (Major GI bleeding (upper and lower), Major Urogenital bleeding, Major Other bleeding), Transient ischemic attack (TIA), Myocardial infarction (MI),Venous

thromboembolism (VTE, deep vein thrombosis DVT or pulmonary embolism PE), Death (all cause)

Data analysis plan

Patients will be followed until OAC discontinuation/switch, disenrollment, death, or study end (whichever occurs first). Baseline characteristics for the study cohorts will be described and compared for the dabigatran (DE) and warfarin cohorts before and after propensity score matching (PSM). Inferential statistics will be used to analyze post-match differences between cohorts. For categorical variables, chi-square tests will be used, and for interval variables, t-tests or, if distribution is not normal, Wilcoxon rank sum test will be conducted. For the comparison of baseline characteristics before and after PSM, a conventional alpha of 0.05 and two-tailed level of significance will be used unless otherwise specified. To compare the occurrence of primary and secondary outcomes between DE and warfarin cohorts, time to event will be investigated using non-parametric Kaplan-Meier (KM) survival analyses. Cox proportional hazards models will be implemented if the PSM leaves imbalance.

Data management

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