The Comparative Safety and Effectiveness of Warfarin and Dabigatran Utilized in the Humana Non-Valvular Atrial Fibrillation Patient Population-A Retrospective Database Analysis (Safety of Dabigatran vs. Warfarin in NVAF Patients)

First published: 10/09/2015

Last updated: 02/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS10945

Study ID

10946

DARWIN EU® study

No

Study countries

United States

Study description

This study is an opportunity for Boehringer Ingelheim Pharmaceuticals Inc. to collaborate with Humana to conduct comparative safety and effectiveness studies of dabigatran and warfarin using real world data from Humana's health plan operations.

Study status

Ongoing

Research institutions and networks

Institutions

Comprehensive Health Insights

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Shannon Reynolds

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/05/2013

Actual: 31/05/2013

Study start date

Planned: 22/01/2014

Actual: 28/10/2014

Date of final study report

Planned: 29/04/2016

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

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 Humana population.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

DABIGATRAN ETEXILATE

WARFARIN SODIUM

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, uncertain classification) measured as a dichotomous outcome. Major hemorrhage, the occurrence of any one or more of the hemorrhagic events listed below in the follow up period measured as a dichotomous outcome, Hemorrhagic stroke, Major intracranial bleeding, Major extracranial bleeding, Major GI bleeding, Major upper GI bleeding, Major lower GI bleeding, Major urogenital bleeding, Major other bleeding, TIA, MI, VTE (DVT or PE), DVT, PE, Death (all-cause)emic stroke

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Data analysis plan

To account for potential selection bias, the study cohorts (dabigatran and warfarin) will be matched on their baseline characteristics using the propensity score matching (PSM) method, and to account for the length of diagnosis, an additional characteristic named, “Duration of AF” will be used. o compare the occurrence of primary outcomes and secondary outcomes between dabigatran and warfarin cohorts, time to event will be investigated using non-parametric Kaplan-Meier (KM) survival analyses. Cox proportional hazards models will be implemented to evaluate the association between time to event and OAC

treatment while adjusting for appropriate covariates if the propensity score matching leaves imbalance between the groups.

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 source(s), other

Comprehensive Health Insights Inc United States

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