The Comparative Safety and Effectiveness of dabigatran, versus rivaroxaban, and apixaban Utilized in the Department of Defense (DoD) Non-Valvular Atrial Fibrillation Patient Population-A Retrospective Database Analysis

First published: 02/12/2016

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16528

Study ID

24713

DARWIN EU® study

No

Study countries

United States

Study description

The purpose of this study is to assess the safety and effectiveness of newly initiated dabigatran among patients diagnosed with non valvular atrial fibrillation (NVAF) in comparison to newly initiated rivaroxaban users and newly initiated apixaban users

Study status

Finalised

Research institutions and networks

Institutions

Late Stage Research, inVentiv Health Clinical

United Kingdom

First published: 04/10/2013

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Michaela Petrini michaela.petrini@boehringer-ingelheim.com

Study contact

michaela.petrini@boehringer-ingelheim.com

Primary lead investigator

Petrini Michaela

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 12/10/2016

Actual: 12/10/2016

Study start date

Planned: 19/10/2016

Actual: 19/10/2016

Data analysis start date

Planned: 27/01/2017

Actual: 30/01/2017

Date of final study report

Planned: 29/06/2018

Actual: 04/06/2018

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

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:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess the safety and effectiveness of newly initiated dabigatran among patients diagnosed with NVAF in comparison to newly initiated rivaroxaban users and newly initiated apixaban users in two (2) separate study cohorts:• dabigatran vs. rivaroxaban • dabigatran vs. apixaban

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

DABIGATRAN ETEXILATE

RIVAROXABAN

APIXABAN

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Patients diagnosed with non valvular atrial fibrillation (NVAF) with newly initiated dabigatran or rivaroxaban or apixaban.

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

Patients with atrial fibrillation

Estimated number of subjects

47000

Study design details

Outcomes

• Stroke overall (hemorrhagic, ischemic, uncertain)• Major bleeding, overall, Secondary outcomes• Ischemic stroke• Hemorrhagic stroke• Major intracranial bleeding• Major extracranial bleedingo Major GI bleedingo Major other bleeding• TIA• All-cause mortality

Data analysis plan

The target population will include OAC treatment naïve NVAF patients with at least one prescription claim for dabigatran, rivaroxaban or apixaban. For each

patient treated with a NOAC, the date of the first NOAC prescription (index exposure) will serve as the index date. Only those patients whose index date occurs between the respective study periods will be included. The 12-month period prior to the index date will be defined as the pre-index period. The patients will be required to have a NVAF diagnosis in the pre-index period (including index date).

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

Unknown