Comparative Effectiveness and Safety between Warfarin and Dabigatran Using Real World Claims data of Japanese Non-valvular Atrial Fibrillation Patients

First published: 26/07/2017

Last updated: 18/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS20047

Study ID

21672

DARWIN EU® study

No

Study countries

☐ Japan

Study description

A non-interventional study based on existing health insurance claims data to compare the effectiveness (stroke/SE) and safety (major bleeding) in patients with atrial fibrillation and newly treated with dabigatran and warfarin in the real world Japanese setting using a claims database

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Yasuhisa Ono yasuhisa.ono@boehringer-ingelheim.com

Study contact

yasuhisa.ono@boehringer-ingelheim.com

Primary lead investigator

Yasuhisa Ono

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/08/2017

Actual: 17/08/2017

Study start date
Planned: 24/08/2017

Actual: 24/08/2017

Data analysis start date
Planned: 14/10/2017

Actual: 10/11/2017

Date of final study report
Planned: 29/09/2017

Actual: 14/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim

Study protocol

20170531_Protocol-Dabi VKA Comparison draft.pdf (526.1 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

A non-interventional study based on existing health insurance claims data

Main study objective:

To compare the effectiveness (stroke/SE) and safety (major bleeding) in patients with atrial fibrillation and newly treated with dabigatran and warfarin in the real world Japanese setting using a claims database

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

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AA03) warfarin

warfarin

Medical condition to be studied

Population studied

Short description of the study population

Inclusion criteria

1. >18 year-old with confirmed diagnosis of NVAF (International Classification of Diseases (ICD) 10 code I48)
2. New starters of either dabigatran or warfarin
3. No prescription of other OACs for 12 months prior to the index date, defined as the first prescription of OACs (the period is defined as baseline period)
4. Having an index date between 14 March 2011 to 30 June 2016

Exclusion criteria

1. Having less than 12 months of enrolment prior to the index date
2. Dialysis or kidney transplant recipients in baseline period
3. Having atrial flutter, valvular atrial fibrillation (AF), mechanical valve placement, rheumatic AF, mitral valve prolapse/regurge/stenosis in baseline period
4. Having record of deep vein thrombosis or pulmonary embolism < 6 months before AF diagnosis in baseline period

---

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

9000

Study design details

Setting

MDV clinical database between April 2010 and June 2016 was used.

Outcomes

stroke, systemic embolism, Bleeding related events, myocardial infarction

Data analysis plan

This study plans no formal hypothesis testing. The planned analyses are descriptive in nature and results are to be interpreted in an exploratory manner. 1:1 Propensity score matching (PSM) was conducted to to address potential channelling bias. Outcomes will be assessed in the PSM sample.Patient characteristics prior to and after propensity score matching will be described stratified by treatment groupNumber of observed events, number of patient years, the corresponding incidence rates and their 95% confidence intervals (CIs) will be reported.Dabigatran and warfarin outcomes will be compared by estimating the hazard ratios (HRs) for the outcomes and their CIs using Cox regression.Kaplan-Meier curves for event-free survival will be estimated.

Documents

Study results

1160-0288_Synopsis.pdf (375.68 KB)

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