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

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Study Ongoing

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

Ongoing

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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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

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

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

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

9000

Study design details

Outcomes

stroke, systemic embolism, Bleeding related events, myocardial infarction

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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.

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