Comparison of the length of stay in patients hospitalized and initiated with dabigatran or warfarin for a concomitant Non-Valvular Atrial Fibrillation in real-world Japanese therapeutic practice (SHORT-J Study)

First published: 20/07/2016

Last updated: 12/12/2025

Study Finalised

Administrative details

EU PAS number

EUPAS13462

Study ID

18496

DARWIN EU® study

No

Study countries

Japan

Study description

The primary objective of this study is to compare the LoS from treatment of oral anticoagulant initiation to hospital discharge of patients hospitalized and subsequentlytreated with dabigatran or warfarin for non-valvular atrial fibrillation in a real-world Japanese clinical practice. The secondary objective of the study is to compare LoS of patients hospitalized with 1) acute ischemic stroke, and 2) due to non-valvular atrial fibrillation. Other objectives are (1) to compare the in-hospital direct and indirect-related costs between dabigatran and warfarin, and (2) to compare the rates of patients directly discharged at home after the index hospitalization between dabigatran and warfarin.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Taku Fukaya

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/07/2016

Actual: 25/07/2016

Study start date

Planned: 01/08/2016

Actual: 02/09/2016

Data analysis start date

Planned: 13/06/2016

Actual: 02/09/2016

Date of final study report

Planned: 30/09/2016

Actual: 14/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co.,Ltd..

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

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to compare the length of stay (LoS) of patients hospitalized and subsequently treated with dabigatran or warfarin for a non-valvular atrial fibrillation (NVAF) in a real-world Japanese therapeutic practice in patients with NVAF.

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 POTASSIUM

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

(B01AA03) warfarin

warfarin

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Patients hospitalized and initiated with dabigatran or warfarin for a concomitant Non-Valvular Atrial Fibrillation in real-world Japanese therapeutic practice.

Age groups

- Adolescents (12 to < 18 years)
- 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

1600

Study design details

Outcomes

The secondary objective of this study is to compare the LoS of patients hospitalized with 1) acute ischemic stroke, and 2) due to NVAF.

Data analysis plan

Analyses of patient background data, LoS and cost information will be conducted using propensity score matching analysis. Differences of patient background data in dabigatran or warfarin users will be assessed using standardized difference and treatment effect of dabigatran against warfarin on LoS and cost will be assessed using confidence intervals as well as descriptive p-values.

Documents

Study results

1160-0254_Synopsis.pdf (239 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)

Other

Data sources (types), other

Insurance claims and diagnostic procedure combination (DPC) data provided by Medical Data Vision Co. Ltd (MDV).

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