Treatment Patterns of newly initiated oral anticoagulants on Japanese non-vascular atrial fibrillation patients using a Japanese claims database

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Study Finalised

Administrative details

EU PAS number

EUPAS16392

Study ID

16393

DARWIN EU® study

No

Study countries

☐ Japan

Study description

A retrospective, observational study using health insurance claims data to describe the prescription pattern of oral anticoagulants in Japanese patients with atrial fibrillation. The primary outcome is the type and dose of oral anti-coagulant (warfarin, apixaban, rivaroxaban, dabigatran and edoxaban). The secondary outcome is the patient baseline characteristics of Japanese NVAF patients in each oral anticoagulant cohort. The datasource is Medical Data Vision's claims data containing approximatley 480,000 Japanese patinent data with diagnostic claim of atrial fibrillation. The study includes new starters of anti-coagulants wihtout prior treatment of oral anticoagulant with AF. PS matching between warfarin and dabigatran exposed groups will be conducted based on baseline characteristics and concurrent drug treatment as co-variates.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

Study institution contact

Yasuhisa Ono yasuhisa.ono@boehringer-ingelheim.co.jp

Study contact

yasuhisa.ono@boehringer-ingelheim.co.jp

Primary lead investigator

Yasuhisa Ono

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/11/2016

Actual: 24/11/2016

Study start date

Planned: 24/11/2016

Data analysis start date

Planned: 29/11/2016

Date of final study report

Planned: 22/12/2016

Actual: 07/07/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippong Boehringer Ingelheim

Study protocol

non-interventional-study-protocol-oacs-PDFfinal.pdf (148.16 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:

Disease epidemiology

Drug utilisation

Data collection methods:

Primary data collection

Study design:

A retrospective, observational study using health insurance claims data

Main study objective:

The main objective to evaluate the number of non-valvular atrial fibrillation patients newly treated with oral anticoagulants between the period of March 2011 to June 2016 and type/dose of oral anti-coagulants these patients have received.

Study drug and medical condition

Medicinal product name

ELIQUIS

XARELTO

Medicinal product name, other

warfarin, Prazaxa

Anatomical Therapeutic Chemical (ATC) code

(B01AA03) warfarin

warfarin

(B01AE07) dabigatran etexilate

dabigatran etexilate

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

480000

Study design details

Setting

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

Outcomes

Type and dose of newly prescribed anti-coagulant to AF patients, Patient baseline characteristics including past medical history, demographics and concurrent drug treatment

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Data analysis plan

Descriptive statistics of each oral anti-coagulant for baseline characteristics and treatment status on index date defined as the date of first prescription of anti-coagulant. Exploratory analysis to use propensity score matching method to see if treatment groups can be matched using various co-variates such as clinical history, gender, age, previous and concomittant medication, year and month of index date, time from AF diagnosis, type and dose of oral anti-coagulant.

Summary results

Among the patients diagnosed as NVAF between April 2010 and June 2016, 48,696 patients were prescribed dabigatran, warfarin, apixaban, edoxaban, or rivaroxaban as the first OACs. Among them, the number of eligible patients for those prescribed dabigatran, warfarin, apixaban, rivaroxaban, or edoxaban as the first OAC were 4,943, 12,497, 11,415, 8,767, or 2,272, respectively. Some baseline characteristics such as age distribution, history of hospitalization, some AF risk factor scores, distribution of year of initiating treatment, and some concomitant medication were different among the treatment groups.After propensity score matching based on matching ratio of 1:1, using caliper factor of 0.10, it was confirmed that the distribution of propensity score was similar between the patients prescribed dabigatran and warfarin.The number of matching patients after the matching was 4,421 for both treatment groups. There was no background factor with standardized difference at more than 0.1.

Documents

Study results

1160-0279_Synopsis.pdf (201.52 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