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

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Study Planned

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

Planned

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: 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

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

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

Name of medicine

ELIQUIS

XARELTO

Name of medicine, other

warfarin, Prazaxa

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

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.

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