Comparative Effectiveness of Oral Anticoagulants: A Cohort Study

First published: 16/04/2013

Last updated: 14/04/2015

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/9417

EU PAS number

EUPAS3061

Study ID

9417

DARWIN EU® study

No

Study countries

☐ United States

Study description

This cohort study plans to identify initiators of oral anticoagulants using electronic claims data from a commercial insurance database to quantify associations between anticoagulant choice (warfarin and dabigatran) and the occurrence of selected outcomes in patients with non-valvular atrial fibrillation at risk for stroke.

Study status

Finalised

Research institutions and networks

Institutions

Brigham and Women's Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sebastian Schneeweiss

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/06/2012

Actual: 01/06/2012

Study start date
Planned: 18/04/2013

Actual: 17/04/2013

Data analysis start date
Planned: 22/04/2013

Actual: 22/04/2013

Date of final study report
Planned: 30/09/2013

Actual: 14/04/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

Quantify associations between anticoagulant choice (warfarin and dabigatran) and the occurrence of selected outcomes in patients with non-valvular atrial fibrillation at risk for stroke.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01A) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Patients with non-valvular atrial fibrillation at risk for stroke

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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)

Special population of interest

Other

Special population of interest, other

Patients with atrial fibrillation

Estimated number of subjects

9000

Study design details

Outcomes

StrokeMajor bleeding, Stroke or systemic embolismSystemic embolismIschemic strokeHemorrhagic strokeStroke uncertain classificationMajor intracranial bleeding Major extracranial bleedingMajor GI bleedingMajor upper GI bleedingMajor lower GI bleedingMajor urogenital bleedingMajor other bleedingTransient ischemic attackMyocardial infarctionVenous thromboembolismDVTPulmonary embolism

Data analysis plan

After identifying initiators of warfarin or dabigatran with an existing diagnosis of non-valvular atrial fibrillation and at risk for stroke in a large US commercial claims database we will use propensity score methods and time-to-event analyses to estimate the ratio in hazard rates for each of the outcomes of interest.

Documents

Study report

1160-157--report_ENCEPP.pdf(211.34 KB)

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