A description of warfarin and new oral anticoagulant utilization patterns including initiation, switching, and discontinuation: Phase 3 of the BI/BWH Pradaxa study program (Anticoagulant utilization pattern)

First published: 16/04/2013

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS3064

Study ID

31549

DARWIN EU® study

No

Study countries

☐ United States

Study description

This study plans to describe utilization patterns for oral anticoagulants over time in patients with non-valvular atrial fibrillation at risk for stroke using electronic claims data from a US commercial insurance database

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 interim report, if expected
Planned: 30/06/2013

Date of final study report
Planned: 31/07/2017

Actual: 20/09/2018

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

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:

Provide a description of patients with non-valvular atrial fibrillation at risk for stroke initiating oral anticoagulants and a description of existing utilization

patterns for warfarin and for new oral anticoagulant medications as they become available.

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 ≥18 years with a diagnosis of Non-valvular atrial fibrillation (NVAF) at risk for stroke (CHA2DS2-VASc score ≥ 1) who initiated treatment either with warfarin, dabigatran, rivaroxaban or apixaban between January 2009 and September 2015.

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

Non-valvular atrial fibrillation (NVAF) patients

Estimated number of subjects

100000

Study design details

Outcomes

Proportion of patients dispensed specific anticoagulants and anticoagulant doses (for new oral anticoagulant medications)Description of the characteristics of patients with non-valvular atrial fibrillation initiating oral anticoagulants, Treatment persistence over time

Data analysis plan

Analyses are descriptive. Utilization patterns will be examined overall and in subgroups defined by patient characteristics, incident/former use, and over time. The initial analyses will be based on January 2009- June 2012 data and will be updated at 6-month intervals as more data become available through 2015.

Documents

Study results

1160.177_c25907708-01.pdf(1.68 MB)

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

Unknown