Comparative risk of major bleeding with new oral anticoagulants (NOACs) and Phenprocoumon in patients with atrial fibrillation: a retrospective claims database study in Germany (CARBOS)

First published: 14/10/2015

Last updated: 29/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS11313

Study ID

16728

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The aim of this study is to investigate whether there are differences in the occurrence of major bleeding events in patients with AF under oral anticoagulation therapies in a real-world setting. It will be investigated whether the occurrence of major bleeding events in AF patients under anticoagulant therapy differs between patients treated with VKA (e.g. Phenprocoumon) and patients treated with NOACS, Apixaban, Dabigatran or Rivaroxaban respectively.

Study status

Finalised

Research institutions and networks

Institutions

Health Risk Institute

Contact details

Study institution contact

Astrid Genet astrid.genet@pfizer.com

Study contact

astrid.genet@pfizer.com

Primary lead investigator

Volz Fabian

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 29/05/2015

Actual: 29/05/2015

Study start date
Planned: 16/10/2015

Actual: 16/10/2015

Data analysis start date
Planned: 12/11/2015

Actual: 19/10/2015

Date of final study report
Planned: 30/11/2016

Actual: 28/09/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer and Bristol-Myers Squibb

Study protocol

Study_Protocol_CARBOS_20150922_v1.0.pdf(1.82 MB)

Study_Protocol_CARBOS_20160108_amended.pdf(1.85 MB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

Investigate whether the occurrence of major bleeding events in AF patients under anticoagulant therapy differs between patients treated with VKA and patients treated with NOACS.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional retrospective database analysis

Study drug and medical condition

Name of medicine

ELIQUIS

PRADAXA

XARELTO

Anatomical Therapeutic Chemical (ATC) code

(B01AA04) phenprocoumon

phenprocoumon

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Insured patient who have been prescribed an oral anticoagulant (OAC) therapy within 01.01.2013 and 31.12.2014 because of documented non-valvular atrial fibrillation (NVAF) in the same or preceding quarter of treatment initiation.

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

36700

Study design details

Outcomes

Major bleeding events, Gastrointestinal bleedings eventsany bleeding events“net clinical” combined outcome consisting of stroke, systemic embolism, major bleeding or death from any cause

---

Data analysis plan

Adjusted hazard ratios of the primary and secondary endpoints will be estimated by means of (i) a cox-proportional hazards model and (ii) a marginal structural model (MSM) accounting treatment switching, for time-varying confounders and exposures

Documents

Study results

Summary_of_results.pdf(171.85 KB)

Data management

Data sources

Data source(s), other

Health Risk Institute Germany

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