Comparative risk of major bleeding with new oral anticoagulants (NOACs) and Phenprocoumon in patients with atrial fibrillation – effectiveness analyses added (CARBOS E+)

First published: 28/04/2017

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS18323

Study ID

22064

DARWIN EU® study

No

Study countries

☐ Germany

Study status

Finalised

Research institutions and networks

Institutions

N/A

Contact details

Study institution contact

Edin Basic edin.basic@pfizer.com

Study contact

edin.basic@pfizer.com

Primary lead investigator

Edin Basic

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/10/2016

Actual: 31/10/2016

Study start date

Planned: 13/04/2017

Actual: 13/04/2017

Data analysis start date
Planned: 02/05/2017

Date of final study report
Planned: 31/10/2017

Actual: 19/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer and Bristol-Myers Squibb

Study protocol

Study_Protocol_CARBOS-E+.pdf(717.49 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 topic:

Human medicinal product

Disease /health condition

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 strokes/SE and 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

Study drug International non-proprietary name (INN) or common name

APIXABAN

DABIGATRAN ETEXILATE

RIVAROXABAN

PHENPROCOUMON

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

1. Adult atrial fibrillation (AF) patients who have newly initiated a oral anticoagulants (OAC) therapy (apixaban, dabigatran, rivaroxaban, edoxaban2 or phenprocoumon) within the study period (01.01.2013 - 31.12.20153), i.e. no prior prescription for any of the above listed substances in the 12 months before the first prescription in the study period
2. Have an ambulatory verified or primary or secondary hospital discharge diagnosis of AF (ICD-10 GM I48.0/ I48.1/I48.2/I48.9) in the previous or same quarter of the index date

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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

60500

Study design details

Outcomes

Strokes or systemic embolism and major bleeding events, All StrokesIschemic strokeHaemorrhagic strokeAll-cause mortalityIntracranial bleedingGastrointestinal bleedingany bleeding events

Data analysis plan

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

Documents

Study results

Study_Report_CARBOS-E+.pdf(963.61 KB)

Study publications

Hohnloser SH, Basic E, Nabauer M. Comparative risk of major bleeding with new o…

Data management

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