POST-APPROVAL SAFETY STUDY (PASS) OF THE UTILIZATION PATTERN OF APIXABAN IN THE NETHERLANDS

First published: 18/11/2013

Last updated: 14/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/14470

EU PAS number

EUPAS5184

Study ID

14470

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

This will be a descriptive study using retrospectively collected data from electronic health record databases. The study will describe the utilization pattern of apixaban in the Netherlands (01 Dec 2011 through 31 Dec 2014).

Study status

Finalised

Research institutions and networks

Institutions

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution **Laboratory/Research/Testing facility** **ENCePP partner**

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Stephen Schachterle

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/05/2012

Actual: 21/05/2012

Study start date

Planned: 01/10/2014

Actual: 01/12/2011

Date of final study report

Planned: 31/05/2016

Actual: 20/05/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb, Pfizer

Study protocol

cv185102st-prot (pfizer-protocol-b0661018).pdf(123.8 KB)

cv185102st-prot-may2015-(pfizer-protocol-b0661018)-red.pdf(1.7 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The objective of this study is to describe the utilization patterns of apixaban in the Netherlands.

Study drug and medical condition

Name of medicine

ELIQUIS

Population studied

Short description of the study population

Patients identified in the EHR database who have received an apixaban dispensation during the study period 01 Dec 2011 through 31 Dec 2014.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Estimated number of subjects

896

Study design details

Outcomes

Off label use of apixaban.

Data analysis plan

Descriptive analyses of the data will be conducted. The proportionof patients receiving the drug for indications within and outside the approved label in each of the study years will be estimated and any trend over time will be described.

Documents

Study results

study-cv185102st-csr-final-red.pdf(1000.57 KB)

Data management

Data sources

Data source(s)

PHARMO Data Network

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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