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

Contact details

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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 institution and networks

Institutions

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands
First published: 07/01/2022
Last updated 10/01/2022

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

Study timelines

Date when funding contract was signed

Planned:
21/05/2012
Actual:
21/05/2012

Data collection
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 data collection

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

Results tables
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