Post-Authorisation Safety Study (PASS) of the Utilisation Patterns of Apixaban in Denmark

First published: 16/08/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS14786

Study ID

30580

DARWIN EU® study

No

Study countries

Denmark

Study description

Apixaban (ELIQUIS®) is an orally administered anticoagulant that was approved in the European Union (EU) in May 2011 for the prevention of venous thromboembolic events (VTE) in adults who have undergone elective hip or knee replacement surgery. Subsequently, apixaban received approvals for stroke and systemic embolism (SE) prevention in those with nonvalvular atrial fibrillation (NVAF), and for the treatment and prevention of deep venous thrombosis (DVT) and pulmonary embolism (PE) in adults. This study aims to estimate the proportion of apixaban users in the outpatient settings who receive the drug for the approved indications at the time of the study, and describe the characteristics of the patients who are prescribed apixaban for on-label and off-label indications. These aims will be examined with a descriptive, retrospective, cross-sectional study that uses electronic healthcare data from the Danish national registries. All patients dispensed apixaban as recorded in the Danish Health Services Prescription Database from May 2011 to December 2014 will be included.

Study status

Finalised

Research institutions and networks

Institutions

Aarhus University & Aarhus University Hospital CLINICAL EPIDEMIOLOGY AND DATA SCIENCE, DEPARTMENT OF CLINICAL MEDICINE

Denmark

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Institution | Educational Institution

Contact details

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Study contact

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Primary lead investigator

Vera Ehrenstein

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/08/2016

Actual: 25/08/2016

Study start date

Planned: 31/08/2016

Actual: 31/08/2016

Date of final study report

Planned: 31/08/2017

Actual: 31/07/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bristol-Myers Squibb Company/Pfizer EEIG

Study protocol

cv185524-prot-(pfizer-protocol-B0661073)-RED.pdf (1.24 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 utilisation pattern of apixaban in Denmark with regard to on-label and off-label use.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

APIXABAN

Population studied

Short description of the study population

Any patient receiving apixaban in Denmark recorded in routine outpatient dispensation records.

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)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

8.000

Study design details

Data analysis plan

Data will be collected on apixaban dispensations, prescriber specialty, and patient characteristics such as age, gender, morbidities, concomitant medications, and hospital-based diagnoses and procedures. Patients will be classified as on-label or off-label users if their initial indication has been recorded or can be inferred from the registry data. If an apixaban indication is not present or cannot be inferred from the registries, the patients' indications will be considered unknown. Information will be drawn from the Danish Civil Registration System (DCRS), Danish National Patient Register (DNPR), and the National Health Service Prescription Database (NHSPD).

Documents

Study report

B0661073 Apixaban DUS FINAL REPORT.pdf (1.39 MB)

Study publications

Vinter N, Linder M, Andersen M, Pedersen AB, Madsen M, Schachterle SE, Ataher Q...

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Danish registries (access/analysis)

Data sources (types)

Drug dispensing/prescription data

Other

Data sources (types), other

Electronic healthcare data from the Danish national registries

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