Real-world Evidence of Prolonged Apixaban Treatment of Unprovoked Venous Thromboembolism

First published: 21/08/2018

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Study Finalised

Administrative details

EU PAS number

EUPAS25305

Study ID

31921

DARWIN EU® study

No

Study countries

United States

Study description

The objectives of this study are to describe patient characteristics, treatment patterns and outcomes among unprovoked VTE patients who received apixaban treatment and either continued or discontinued apixaban after 6 months

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Xuemei Luo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 03/01/2018

Actual: 20/03/2018

Study start date

Planned: 21/08/2018

Actual: 18/09/2018

Data analysis start date

Planned: 31/08/2018

Actual: 15/10/2018

Date of final study report

Planned: 01/12/2019

Actual: 31/07/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer/BMS

Study protocol

SIMR_Pfizer_Protocol_Pooled VTE extended_10AUG2018.pdf (923.98 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 type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The objectives of this study are to describe patient characteristics, treatment patterns and outcomes among unprovoked VTE patients who received apixaban treatment and either continued or discontinued apixaban after 6 months

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

APIXABAN

Medical condition to be studied

Population studied

Short description of the study population

Patients were included in the study if they:
a) Had ≥1 medical claim with a primary or secondary unprovoked VTE diagnosis (index VTE event) in the inpatient or ambulatory setting during the identification period (01-Sep-2014 to 31-Dec-2017). The first VTE diagnosis will be identified as the index VTE event. If occurring in the outpatient setting, the index VTE event date will be defined as the service date; if in the inpatient setting, the discharge date will be designated as the index VTE event date. Qualifying outpatient encounters followed by a qualifying inpatient encounter within 7 days will be considered an inpatient episode (unless apixaban was initiated between encounters, in which case the event would be classified as an outpatient encounter);
b) Had ≥1 pharmacy claim for apixaban during the 30-day period following the index VTE event [during 01-Sep-2014-31-Dec-2016 or 6 months prior to study end so that all patients have the opportunity to have six months of use]. Patients will be required to have continuous apixaban use for ≥6 months without a gap of >30 days. The end of the initial 6 months of apixaban treatment following the index VTE event will be designated as the index date;
c) Were aged ≥18 years as of the index date; and
d) Had continuous health plan enrollment for ≥12 months prior to the index date.

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

Renal impaired

Hepatic impaired

Estimated number of subjects

1.000

Study design details

Data analysis plan

Means, medians, and standard deviations will be provided for continuous variables when performing descriptive analysis of continuous data. Numbers and percentages will be provided for dichotomous and polychotomous variables when performing descriptive analysis of categorical data. Bivariate comparisons of baseline characteristics and outcomes measures will be provided. Appropriate tests (eg, t-test, chi-square test) will be used based on the distribution of the measure. The cumulative incidence rate for clinical outcomes (major bleeding, CRNM, recurrent VTE) will be calculated. The incidence rate will be calculated as the number of patients who experience the event divided by the observed time at risk. All data analysis will be executed using statistical software STATA and SAS version 9.3/9.4.

Documents

Study results

SIMR_Pfizer_Pooled_VTE Extended_Study Report_08JULY2019.pdf (654.96 KB)

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 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