Evaluation of the Safety and Effectiveness of Anticoagulants Among Sub-Groups of Venous Thromboembolism Patients (VTE Subgroups)

First published: 18/11/2019

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS32365

Study ID

50355

DARWIN EU® study

No

Study countries

United States

Study description

This study will add real-world evidence regarding demographic and clinical characteristics, risks of major bleeding, clinically relevant non-major bleeding, and recurrent VTE among VTE patients who initiated treatment with apixaban or warfarin, especially among some high-risk subgroups of patients.

Study status

Finalised

Research institutions and networks

Institutions

SIMr STATinMED

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Institution

Contact details

Study institution contact

Xuemei Luo Xuemei.Luo@pfizer.com

Study contact

Xuemei.Luo@pfizer.com

Primary lead investigator

Xuemei Luo

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 23/04/2019

Actual: 23/04/2019

Study start date
Planned: 30/11/2019

Actual: 18/11/2019

Date of final study report
Planned: 15/11/2023

Actual: 14/11/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer/BMS

Study protocol

SIMR_Pfizer_Protocol_Pooled VTE_21Oct2019.pdf (1.1 MB)

Pfizer_Pooled 5 database VTE_Protocol_27APR2020 V2 - Clean.pdf (885.11 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 type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

Describe and compare, among VTE patients overall and in key subgroups of patients who were prescribed apixaban or warfarin, the following:1. demographic and clinical characteristics 2. rate of MB and CRNM bleeding 3. rate of recurrent VTE

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

Venous thrombosis

Population studied

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)

Estimated number of subjects

5000

Study design details

Data analysis plan

Means, medians, and standard deviations will be provided for continuous variables. Numbers and percentages will be provided for dichotomous and polychotomous variables. 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. Kaplan-Meier survival curves will be generated to illustrate the time to first MB, CRNM bleeding, and recurrent VTE events. The cumulative incidence rate for clinical outcomes will be calculated. Inverse probability treatment weighting (IPTW) will be used to balance patient characteristics when comparing outcomes among different cohorts. Cox proportional hazards models will be used to compare the time to recurrent VTE, MB, and CRNM bleeding between apixaban and warfarin cohorts after IPTW. Data analysis will be executed using statistical software SAS version 9.3/9.4

Documents

Study results

B0661144_StudyReport_V1_25May2023_staticToC.pdf (2.53 MB)

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), other

MarketScan United States, Optum United States, IMS PharMetrics Plus United States, Humana United States, US Centers for Medicare & Medicaid Services (CMS) Data United States

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