Comparative Clinical and Economic Outcomes among Venous Thromboembolism Patients who Initiated Apixaban or Warfarin in the United States Medicare Population (VTE CER in Medicare)

First published: 19/07/2018

Last updated: 02/06/2020

Study Finalised

Administrative details

EU PAS number

EUPAS24902

Study ID

35610

DARWIN EU® study

No

Study countries

United States

Study description

This study will evaluate the patient profiles, current antithrombotic patterns, and real-world clinical & economic outcomes among patients with VTE

Study status

Finalised

Contact details

Study institution contact

Patrick Hlavacek patrick.hlavacek@pfizer.com

Study contact

patrick.hlavacek@pfizer.com

Primary lead investigator

Patrick Hlavacek

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 11/09/2017

Study start date

Planned: 01/08/2018

Actual: 08/01/2018

Date of final study report

Planned: 02/06/2020

Actual: 02/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

SIMR_Pfizer_Protocol_Medicare_VTE_07JUNE_clean.pdf (922.32 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

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Healthcare resource utilisation

Data collection methods:

Secondary use of data

Main study objective:

Aim 1: Compare the demographic and clinical characteristics of patients who were prescribed apixaban or warfarin. Aim: 2: Compare both the incidence rates and the risk (using Hazard ratios) of major bleeding between patients who received apixaban versus warfarin.Aim 3: Compare both the incidence rates and the risk of CRNM between patients who received apixaban versus warfarinAdditional

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ELIQUIS

Population studied

Short description of the study population

Elderly (≥65 years) patients diagnosed with Venous thromboembolism (VTE) in the Medicare population, who were prescribed apixaban or warfarin (bridging to warfarin) between September 1, 2014 and December 31, 2016 and had continuous health plan enrolment for 6 months prior to the prescription.

Age groups

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Venous thromboembolism patients

Estimated number of subjects

1

Study design details

Outcomes

Major bleeding, CRNM bleeding, Recurrent VTE, Major bleeding related costs, Recurrent VTE related cost, All cause health care utilization, All cause costs, All cause death

---

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. The cumulative incidence rate for clinical outcomes (major bleeding, CRNM, and recurrent VTE) will be calculated. Propensity score matching will be used to balance patient characteristics of the cohorts. Cox regression models will be used to evaluate the risk of clinical outcomes. Generalized linear models (GLM) and two-part models will be used to compare health care costs between the apixaban and warfarin cohorts. Data analysis will be executed using statistical software SAS version 9.3/9.4.

Documents

Study results

Final Report_Medicare_VTE.pdf (345.28 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