Evaluation of Anticoagulants among Venous Thromboembolism Patients with Active Cancer: Pooled Analysis from Claims Databases

First published: 21/08/2018

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS25308

Study ID

49163

DARWIN EU® study

No

Study countries

United States

Study description

This study will evaluate patient characteristics and the use of apixaban, warfarin, and LMWH use among VTE patients with active cancer.

Study status

Finalised

Contact details

Study institution contact

Michael Cicchetti Michael.Cicchetti@Pfizer.com

Study contact

Michael.Cicchetti@Pfizer.com

Primary lead investigator

Xuemei Luo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2018

Actual: 20/03/2018

Study start date

Planned: 21/08/2018

Actual: 21/10/2018

Data analysis start date

Planned: 31/08/2018

Actual: 21/10/2018

Date of final study report
Planned: 30/11/2023

Actual: 27/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer/BMS

Study protocol

SIMR_Pfizer_Protocol_Pooled VTE cancer_01MAY2019_clean.pdf (1.06 MB)

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:

1: Compare demographic/clinical characteristics of VTE pts w/active cancer prescribed apixaban, LMWH, or warfarin2: Evaluate treatment patterns among VTE pts w/active cancer prescribed apixaban, LMWH, or warfarin.3: Compare the risk of MB, CRNM bleeding & recurrent VTE <6 months & using all available follow-up period among VTE pts w/active cancer prescribed apixaban, LMWH, or warfarin.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

APIXABAN

LOW MOLECULAR WEIGHT HEPARIN SODIUM

WARFARIN

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)

Special population of interest

Renal impaired

Hepatic impaired

Estimated number of subjects

8.000

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. Inverse probability treatment weighting (IPTW) will be used to balance treatment cohorts. 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 bleeding, and recurrent VTE) will be calculated. Cox proportional hazard ratio model will be used to evaluate the risk of clinical outcomes (MB, CRNM bleeding, recurrent VTE). Data analysis will be executed using statistical software SAS version 9.3/9.4.

Documents

Study results

B0661123_Final Study Report_V1_16Oct2023.pdf (3.82 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

Market Scan United States, Pharmetrics United States, Optum United States, Humana 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