Outcomes among venous thromboembolism patients who were admitted into the emergency department and treated with apixaban or warfarin in the U.S. (VTE CER in Premier ED)

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Study Finalised

Administrative details

EU PAS number

EUPAS29963

Study ID

34961

DARWIN EU® study

No

Study countries

United States

Study description

This study will evaluate real-world outcomes among patients with VTE admitted into the emergency department and treated with either apixaban or warfarin.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Patrick Hlavacek

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/01/2019

Study start date

Planned: 26/06/2019

Actual: 26/06/2019

Date of final study report

Planned: 20/06/2020

Actual: 06/04/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

PremierDB_Hospital_VTE_ED_Protocol_vfinal.pdf (577.08 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:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

• To evaluate the ED discharge status, hospital healthcare resource utilization and costs of VTE patients • To evaluate 1-month all-cause, major bleeding (MB)-related, any bleeding-related, and VTE-related readmission rates of VTE patients• To determine hospital LOS and costs associate with all-cause, MB-related, any bleeding-related, and VTE related readmissions within 1 month after index

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ELIQUIS

Medical condition to be studied

Venous thrombosis

Pulmonary embolism

Population studied

Short description of the study population

Adult patients ≥18 years of age admitted into a hospital ED with a primary discharge International Classification of Diseases (ICD)-9 or ICD-10 diagnosis code of venous thromboembolism (VTE) were identified from the Premier Hospital database from August 1, 2014 through May 31, 2018. Patients who received apixaban or warfarin during the ED visit were selected and grouped into two study cohorts according to the OAC received. Patients treated with warfarin were additionally required to have received ≥1 injectable anticoagulant, including LMWH, UFH, or fondaparinux, during ED admissions. The first of such VTE ED admissions was defined as the index event, with the corresponding ED or hospital discharge date as the index date. Patients who received both apixaban and warfarin or any other DOAC (rivaroxaban, dabigatran, edoxaban, betrixaban) during their index ED admission, or were diagnosed with atrial fibrillation/atrial flutter or pregnancy during the 12-month baseline period prior to the index event or during the index event, or had inferior vena cava filter usage during the baseline period or index event, or were transferred from other facilities, or died during the index event were excluded from the study population.

Patients must have met all the following inclusion criteria to be eligible for inclusion in the study:

• Have a primary diagnosis of VTE identified by the following ICD-9-CM or ICD-10 codes from the Premier Hospital database between August 1, 2014 and May 31, 2018

o Pulmonary embolism (PE)

o Deep vein thrombosis (DVT)

• Received either apixaban or warfarin prior to discharge from the ED

o Patients receiving warfarin were further required to have received at least one of the injectable anticoagulants, including LMWH, UFH, or fondaparinux, during their ED admission.

• Have an age ≥18 years as of the index ED admission for VTE

Patients meeting any of the following criteria were not included in the study:

• Received both apixaban and warfarin during the index ED admission. This exclusion criterion allowed for a clean grouping of patients into the apixaban and warfarin cohorts.

• Received any other DOAC, including rivaroxaban, dabigatran edoxaban and betrixaban, during the index ED admissions.

• Had medical claims indicating one of the following conditions or procedures during the index ED admission or within 12 months prior to the index date:

1. Atrial fibrillation (AF)/ Atrial flutter (AFL)
2. Pregnancy
3. Inferior vena cava filter (IVCF) usage:

• Patients transferred from other facilities.

• Patients who died during the index ED admission.

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

Other

Special population of interest, other

Venous thromboembolism patients

Estimated number of subjects

1

Study design details

Outcomes

ED discharge status, ER resource utilization, all cause readmission, MB-related readmission, VTE-related readmission, any-bleeding-related readmission

Data analysis plan

Bivariate descriptive statistics will be utilized to describe demographics, clinical characteristics, readmission rates, and unadjusted resource utilization and costs among each patient cohort. Means, medians, and standard deviations will be provided for continuous variables when performing descriptive analysis of continuous data. A multivariable logistic regression analysis will be carried out to assess the potential impact of treatment with warfarin compared to treatment with apixaban on index ED discharge status as well as 1-month all-cause, MB-related, any bleeding-related and VTE-related readmission risks, separately. A generalized linear model (GLM) will be used examine the impact of treatment with warfarin vs. apixaban on index event LOS and hospital readmission LOS. A two-part model analysis will be used examine the impact of treatment with warfarin vs. apixaban on 1-month MB-related and VTE-related readmission costs.

Documents

Study results

VTE_ED_Apixaban_Warfarin_Report_New_Template_v7 final 4-6-20.pdf (574.01 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