

# 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

### PURI

<https://redirect.ema.europa.eu/resource/34961>

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### EU PAS number

EUPAS29963

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### Study ID

34961

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### DARWIN EU® study

No

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## Study countries

☐ United States

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## 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.

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## 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

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## Study start date

Planned: 26/06/2019

Actual: 26/06/2019

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## 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

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### 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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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

**Name of medicine**

ELIQUIS

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**Medical condition to be studied**

Venous thrombosis

Pulmonary embolism

## Population studied

**Short description of the study population**

Adult patients  $\geq 18$  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  $\geq 1$  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  $\geq 18$  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.

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### **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)

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### **Special population of interest**

Other

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### **Special population of interest, other**

Venous thromboembolism patients

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### **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

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### **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)

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## Data management

### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No