# Venous Thromboembolism Treatment (VOLT)

**First published:** 29/05/2019

Last updated: 14/06/2024





## Administrative details

EU PAS number	
EUPAS29910	
Study ID	
47198	
DARWIN EU® study	
No	
Study countries	
Finland	
Norway	
Sweden	

#### **Study description**

A retrospective, observational study of patients prescribed an OAC following a VTE event after the 1 January 2013 or the marketing date of NOACs in each country, whichever occurs last, using nationwide registries from multiple Nordic countries (Sweden, Norway, and Finland).

#### **Study status**

Ongoing

## Research institutions and networks

#### **Institutions**

Evidera
United Kingdom
First published: 20/11/2013
Last updated: 07/03/2024
Institution
ENCePP partner

### Contact details

#### **Study institution contact**

Jenkins Aaron Rupesh.Subash@pfizer.com

Study contact

#### Rupesh.Subash@pfizer.com

## Primary lead investigator

#### Jenkins Aaron

**Primary lead investigator** 

## Study timelines

#### Date when funding contract was signed

Planned: 03/05/2018

Actual: 03/05/2018

#### Study start date

Planned: 01/07/2019

Actual: 02/12/2019

#### **Date of final study report**

Planned: 30/06/2023

## Sources of funding

• Pharmaceutical company and other private sector

## More details on funding

BMS/Pfizer

## Regulatory

#### Was the study required by a regulatory body?

No

#### Is the study required by a Risk Management Plan (RMP)?

Not applicable

## Other study registration identification numbers and links

B0661132

## Methodological aspects

## Study type

## Study type list

#### Study type:

Non-interventional study

#### Scope of the study:

Effectiveness study (incl. comparative)

#### Main study objective:

Phase I involves a descriptive assessment of patient characteristics and treatment patterns in each country as well as detailed power calculations. If the study is adequately powered for comparative analyses, it will proceed to Phase II. Phase II involves analyses of comparative effectiveness and safety, utilising

warfarin as the comparator.

## Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

This is a retrospective, observational, nationwide cohort study using administrative registry data.

## Study drug and medical condition

#### Name of medicine

**ELIQUIS** 

LIXIANA

**PRADAXA** 

**XARELTO** 

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

**WARFARIN** 

#### Medical condition to be studied

Deep vein thrombosis

Pulmonary embolism

## 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**

20000

## Study design details

#### **Outcomes**

Primary efficacy, Recurrent VTE Primary safety, Major Bleeding, Treatment interruption, Complete treatment discontinuation, Treatment switching, Treatment persistence, GI bleeding, intracranial haemorrhage, other bleeding, health care resource utilisation

#### **Data analysis plan**

Phase I of this study would be descriptive in nature, including the number, percentage of patients who discontinue, interrupt, and switch treatment. Patient characteristics will be summarised using numbers and percentages for categorical values and descriptive statistics (mean, SD, median, minimum, maximum and IQR) for continuous. Descriptive analyses will also be performed for specific subgroups. Phase II involves comparative safety and effectiveness analyses, which for this study includes a number of clinical endpoints (recurrent VTE, major bleeding, overall and by site (GI, ICH, other sites) and health care resource utilisation.

## Data management

#### Data sources

#### Data source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

#### Data source(s), other

The Swedish prescribed drug register, NorPD

#### **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