Venous Thromboembolism Treatment (VOLT)

First published: 29/05/2019

Last updated: 14/06/2024

Study Ongoing

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 | **Laboratory/Research/Testing facility** | **Non-Pharmaceutical company** | **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

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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