Real World Evaluation of Venous Thromboembolism (VTE): Analysis of Electronic Health Record Data

First published: 22/09/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS15478

Study ID

25329

DARWIN EU® study

No

Study countries

United States

Study description

This is a retrospective cohort analysis of adult VTE patients on an oral anticoagulant using US EHR data. The study will capture demographic and clinical data from January 1, 2008 to December 31, 2015.

Study status

Finalised

Research institutions and networks

Institutions

Boston Health Economics

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Xuemei Luo

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 13/09/2016

Actual: 13/09/2016

Study start date
Planned: 25/10/2016

Actual: 14/07/2016

Date of final study report
Planned: 30/09/2017

Actual: 03/11/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer, Inc.

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To assess OAC treatment patterns among patients with newly diagnosed VTE.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective Cohort Study

Study drug and medical condition

Medicinal product name

ELIQUIS

PRADAXA

XARELTO

Medicinal product name, other

Coumadin

Medical condition to be studied

Venous thrombosis

Population studied

Short description of the study population

Adults with VTE on or after September 1, 2014 newly treated with an oral anticoagulant and who had at least one medical encounter in the 12 months prior to
the baseline period.

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

Patients with venous thrombosis

Estimated number of subjects

17000

Study design details

Outcomes

Predictors of NOAC use. VTE recurrence and bleeding-related events during follow-up.

Data analysis plan

Descriptive analyses, including means, medians, and standard deviations will be conducted 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. Appropriate tests will be used based on the distribution of the measure. The cumulative incidence rate for clinical outcomes will be calculated. Multivariate analyses will be conducted.

Documents

Study results

VTE Study Report (EU PAS).pdf (714.31 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)

Electronic healthcare records (EHR)

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