Anticoagulant treatment patterns and outcomes among venous thrombosis patients in France: a retrospective cohort analysis using SNDS database

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50097

EU PAS number

EUPAS35888

Study ID

50097

DARWIN EU® study

No

Study countries

France

Study description

A retrospective cohort study to describe anticoagulant (AC) treatment patterns and health outcomes in patients with venous thromboembolism (VTE), using the French national health data system (SNDS).

Study status

Ongoing

Research institutions and networks

Institutions

Evidence and Access/Analytica Laser, Certara

France

United Kingdom (Northern Ireland)

First published: 24/05/2021

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Primary lead investigator

Ruth Mokgokong

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/07/2019

Actual: 05/07/2019

Study start date

Planned: 30/09/2020

Actual: 31/07/2020

Data analysis start date

Actual: 30/09/2020

Date of final study report

Planned: 28/02/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer/BMS

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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To describe anticoagulant treatment patterns and outcomes in patients with venous thromboembolism (VTE), using the French national health data system (SNDS), in two phases. Phase 1 involves descriptive analyses of patients' characteristics and treatment patterns for VTE patients, with and without active cancer. Phase 2 involves comparative effectiveness and safety analyses (only if powered)

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

WARFARIN

ACENOCOUMAROL

FLUINDIONE

HEPARIN

LOW MOLECULAR WEIGHT HEPARIN CALCIUM

LOW MOLECULAR WEIGHT HEPARIN SODIUM

FONDAPARINUX

ARGATROBAN

APIXABAN

RIVAROXABAN

Medical condition to be studied

Venous thrombosis

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

24000

Study design details

Outcomes

Primary efficacy, Recurrent VTE Primary safety, Major Bleeding, Treatment discontinuation, Treatment switching

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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, 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 analyses, which for this study includes a number of clinical endpoints (recurrent VTE, major bleeding). Subgroup analyses are also planned.

Data management

Data sources

Data source(s), other

SNDS France

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