Real-world comparative effectiveness of rivaroxaban versus heparin and phenprocoumon for the treatment and secondary prevention of venous thromboembolism (RECENT)

First published: 30/06/2020

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS36102

Study ID

46933

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The primary objective of this study is: - To assess the risk of recurrent venous thromboembolic (VTE) events in VTE patients treated with rivaroxaban compared to patients treated with low-molecular-weight heparin (LMWH) and Phenprocoumon The secondary objective of this study is: - To assess the risk of fatal bleeding in VTE patients treated with rivaroxaban compared to patients treated with LMWH and Phenprocoumon

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Bayer Clinical Trials BAYER AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2020

Actual: 01/06/2020

Study start date

Planned: 31/07/2020

Actual: 08/07/2020

Date of final study report

Planned: 23/08/2021

Actual: 10/01/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

21456_EU PAS_study protocol.pdf(2.71 MB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to assess the risk of recurrent venous thromboembolic (VTE) events in VTE patients treated with rivaroxaban compared to patients treated with low-molecular-weight heparin (LMWH) and phenprocoumon

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B01AA03) warfarin

warfarin

(B01AB01) heparin

heparin

(B01AF01) rivaroxaban

rivaroxaban

(B01AX05) fondaparinux

fondaparinux

Medical condition to be studied

Pulmonary venous thrombosis

Embolism venous

Population studied

Short description of the study population

The source population of this study will include all insured members of more than 60 German statutory health insurances (SHIs) contributing data to the InGef database.

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

Renal impaired

Estimated number of subjects

25000

Study design details

Outcomes

The effectiveness outcome, recurrent VTE will be analyzed (primary objective) as primary outcome. Safety outcomes include fatal bleeding (secondary objective), and end stage renal disease (other objectives)

Data analysis plan

Researcher in this study want to compare the effectiveness of Rivaroxaban (Xarelto) versus low-molecular-weight heparin (LMWH) and phenprocoumon for the treatment and secondary prevention of venous thromboembolism by evaluating routine clinical practice data from research database in Germany.

VTE is defined by a blood clot in the leg or lower extremity (deep vein thrombosis) or a blood clot in the lung (pulmonary embolism). Treatment of VTE traditionally consists of acute anticoagulation treatment with heparin (mainly LMWH), followed by maintenance oral anticoagulation with vitamin-K antagonists (in Germany mainly phenprocoumon). Rivaroxaban, a direct-acting oral anticoagulants (DOAC), is an alternative VTE treatment and has been approved for both the acute and maintenance phase of VTE treatment. The study will enroll adult male or female patients who are newly diagnosed with VTE and are already on the treatment with Rivaroxaban or LMWH and phenprocoumon.

Documents

Study results

21456_EU PAS Register_Abstract.pdf(442.55 KB)

Study report

OS_Report_21456_RECENT_FINAL_redacted.pdf(3.7 MB)

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)

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