

# 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

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### Study ID

46933

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### DARWIN EU® study

No

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### Study countries

 Germany

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## 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

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## Study status

Finalised

## Research institutions and networks

### Institutions

**Bayer AG**

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

## Contact details

### Study institution contact

Bayer Clinical Trials BAYER AG clinical-trials-contact@bayer.com

**Study contact**

[clinical-trials-contact@bayer.com](mailto:clinical-trials-contact@bayer.com)

### **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

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### **Study start date**

Planned: 31/07/2020

Actual: 08/07/2020

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### **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

## Regulatory

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

No

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### **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

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##### **Study type:**

Non-interventional study

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##### **Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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

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**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.

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### **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)
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### **Special population of interest**

Renal impaired

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### **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)

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### **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)

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### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No