

# A pharmacoepidemiological study of Rivaroxaban use and potential adverse outcomes in routine clinical practice in the United Kingdom

**First published:** 14/10/2015

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS11299

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### Study ID

43192

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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

This prospective cohort study will provide information about: Characteristics of Rivaroxaban use in patients who are prescribed Rivaroxaban for the first time compared to patients who are prescribed standard of care for the first time. The occurrence of intracranial haemorrhage, gastrointestinal and urogenital bleeding, and the occurrence of non-infective liver disease.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Fundación Centro Español de Investigación Farmacoepidemiológica (CEIFE)

 Spain

**First published:** 15/03/2010

**Last updated:** 15/02/2024

**Institution**

**Not-for-profit**

**ENCePP partner**

## Contact details

### Study institution contact

Luis Alberto García Rodríguez [info@ceife.es](mailto:info@ceife.es)

**Study contact**

[info@ceife.es](mailto:info@ceife.es)

## Primary lead investigator

Luis Alberto García Rodríguez

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 30/01/2012

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### Study start date

Actual: 22/12/2011

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### Date of final study report

Planned: 15/11/2020

Actual: 26/11/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer HealthCare AG

## Study protocol

[16647\\_THIN\\_Rivaroxaban protocol.pdf](#) (797.48 KB)

## Regulatory

## Was the study required by a regulatory body?

Yes

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## Is the study required by a Risk Management Plan (RMP)?

EU RMP category 1 (imposed as condition of marketing authorisation)

## 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

Drug utilisation

Effectiveness study (incl. comparative)

#### Data collection methods:

Secondary use of data

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#### Main study objective:

To assess patterns of drug utilization and to quantify outcomes related to safety and effectiveness in new users of rivaroxaban compared with new users of standard of care in routine clinical practice in the UK.

## Study Design

### **Non-interventional study design**

Cohort

## Study drug and medical condition

### **Medicinal product name**

XARELTO

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

RIVAROXABAN

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### **Anatomical Therapeutic Chemical (ATC) code**

(B01A) ANTITHROMBOTIC AGENTS

ANTITHROMBOTIC AGENTS

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### **Medical condition to be studied**

Venous thrombosis

Pulmonary embolism

Atrial fibrillation

Acute coronary syndrome

## Population studied

## **Short description of the study population**

All patients aged 2 years and above who have been enrolled in The Health Improvement Network (THIN) database for at least 1 year and had their first prescription recorded in the database at least 1 year ago will be included.

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### **Age groups**

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
  - 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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### **Estimated number of subjects**

20000

## **Study design details**

### **Outcomes**

1. Descriptive analysis of demographic and clinical characteristics of patients who are prescribed oral rivaroxaban for the first time in comparison with those who are prescribed standard of care for the first time 2. Characteristics of rivaroxaban use in comparison with standard of care (NOTE: please refer to <https://clinicaltrials.gov/> for description of further primary outcomes), 1. Safety: occurrence of bleeding events leading to hospitalization not specified as primary safety outcomes ("other bleeding") in individuals receiving rivaroxaban, in comparison with those receiving current standard of care. (NOTE: please

refer to <https://clinicaltrials.gov/> for description of further secondary outcomes)

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### **Data analysis plan**

For descriptive purposes, annualized crude incidence rates of the specified outcome Events will be calculated, accompanied by 95% confidence intervals.

## Documents

### **Study results**

[Combined Report\\_16159\\_16646\\_16647\\_17543\\_EU PAS](#)

[Abstract\\_Redacted\\_V1.0\\_2020-11-26.pdf](#) (152.16 KB)

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### **Study report**

[16647\\_Progress report\\_v1.0.\\_2019-01-28.pdf](#) (93.11 KB)

[Xarelto PASS - Combined](#)

[Report\\_16159\\_16646\\_16647\\_17543\\_redacted\\_final.pdf](#) (592.92 KB)

### **Study, other information**

[Xarelto PASS - Combined](#)

[Report\\_16159\\_16646\\_16647\\_17543\\_redacted\\_final.pdf](#) (592.92 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 source(s)**

THIN® (The Health Improvement Network®)

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**Data sources (types)**

Drug dispensing/prescription data

Electronic healthcare records (EHR)

## 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