A pharmacoepidemiological study of Rivaroxaban use and potential adverse outcomes in routine clinical pratice in the Netherlands

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## Administrative details

EU PAS number	
EUPAS11141	
Study ID	
43223	
DARWIN EU® study	
No	
Study countries  Netherlands	

#### **Study description**

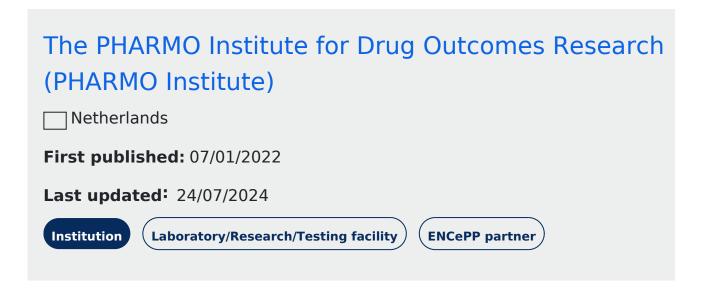
This prospective cohort study will provide information about: Characteristics of Rivaroxaban use in patients who are prescribed Rivaroxaban for the first time compared to patients who are prescribed standard of care for the first time The occurrence of intracranial haemorrhage, gastrointestinal and urogenital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

### **Study status**

**Finalised** 

## Research institutions and networks

### Institutions



## Contact details

### **Study institution contact**

Ron Herings clinical-trials-contact@bayer.com

Study contact

#### clinical-trials-contact@bayer.com

### **Primary lead investigator**

## Ron Herings

**Primary lead investigator** 

## Study timelines

#### Date when funding contract was signed

Actual: 30/01/2012

#### Study start date

Actual: 01/02/2012

### Date of final study report

Actual: 26/11/2020

## Sources of funding

Pharmaceutical company and other private sector

## More details on funding

Bayer HealthCare AG

# Study protocol

16646\_PHARMO\_Rivaroxaban protocol.pdf(702.54 KB)

# Regulatory

Was	the	study	required	by	a reg	gulatory	body?
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Yes

### 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

### Study type:

Non-interventional study

### 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

### 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 Netherlands.

# Study Design

### Non-interventional study design

Cohort

## Study drug and medical condition

#### Name of medicine

**XARELTO** 

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

**RIVAROXABAN** 

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

(B01A) ANTITHROMBOTIC AGENTS
ANTITHROMBOTIC AGENTS

#### 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 registered in the database for at least 1 year before the index date will be included.

#### 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)

#### Special population of interest

Renal impaired

#### **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), 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)

#### 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

EUPAS11141-43170.pdf(152.16 KB)

### **Study report**

16646\_Progress Report\_v1.0\_2019-01-28.pdf(93.28 KB) EUPAS11141-43221.pdf(592.92 KB)

## Data management

## Data sources

#### Data source(s)

PHARMO Data Network

#### 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

### **Check completeness**

Unknown

### **Check stability**

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No