

# Real-world comparative effectiveness of stroke prevention in patients with atrial fibrillation treated with rivaroxaban vs. vitamin k antagonists (RELOAD)

**First published:** 12/10/2016

**Last updated:** 01/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS15755

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### Study ID

28914

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### DARWIN EU® study

No

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### Study countries

 Germany

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### Study description

The aim of this study is to assess the real world comparative effectiveness of Rivaroxaban prescribed in non-valvular atrial fibrillation (NVAF) routine care patients in Germany.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Germany

## Contact details

### **Study institution contact**

Bayer Clinical Trials Contact 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 Contact BAYER AG

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 28/04/2016

Actual: 28/04/2016

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### **Study start date**

Planned: 15/10/2016

Actual: 15/10/2016

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### **Date of final study report**

Planned: 28/02/2017

Actual: 06/10/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## Study protocol

[18735\\_PRC\\_OS\\_Secondary Data\\_SPAF\\_v2\\_final\\_with signatures\\_2016-10-27.pdf](#)

(3 MB)

## 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 main objective of this study is to assess the risk of ischemic stroke (effectiveness) and intracranial hemorrhage (ICH, safety) in patients treated with Rivaroxaban compared to patients treated with Phenprocoumon

## Study Design

## **Non-interventional study design**

Cohort

# Study drug and medical condition

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

(B01AA04) phenprocoumon

phenprocoumon

(B01AF01) rivaroxaban

rivaroxaban

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## **Medical condition to be studied**

Atrial fibrillation

# Population studied

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

Patients, newly initiated with Rivaroxaban or Phenprocoumon with an non-valvular atrial fibrillation (NVAf) diagnosis from January 1, 2012 through December 31, 2015.

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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

Other

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## Special population of interest, other

Atrial fibrillation patients

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## Estimated number of subjects

99999

# Study design details

## Outcomes

- Risk of ischemic stroke - Risk of intracranial hemorrhage (ICH), - Risk of ischemic stroke or ICH- Risk of systemic embolism (SE)- Risk of transient ischemic attack (TIA)- Risk of ischemic stroke or SE or TIA For more details please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

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## Data analysis plan

Time-to-event analyses using unadjusted and adjusted multivariate cox proportional hazard models and a 1:1 propensity score matched analyses will be conducted to estimate Hazard Ratios and corresponding confidence intervals.

# Documents

## Study results

[18735\\_EUPAS\\_Abstract.pdf](#) (67.96 KB)

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## Study report

[18735\\_Reload\\_Report 2.0final\\_06102017\\_redacted.pdf](#) (2.86 MB)

# Data management

ENCePP Cool

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**

Unknown