

# An Observational Post-authorization Safety Specialist Cohort Event Monitoring Study (SCEM) to Monitor the Safety and Utilization of rivaroxaban (XARELTO®) initiated in secondary care for the prevention of atherothrombotic events in patients who have had acute coronary syndrome in England and Wales (ROSE ACS)

**First published:** 31/07/2015

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

Study

Finalised

## Administrative details

### EU PAS number

EUPAS9977

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### Study ID

35313

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**DARWIN EU® study**

No

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## **Study countries**

 United Kingdom

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## **Study description**

Rivaroxaban is a medicine which reduces the formation of blood clots. Acute coronary syndrome (ACS) comprises a range of disorders, including heart attack and unstable angina, caused by a sudden reduction in blood flow to part of the heart muscle. This study aims to collect information on the use of rivaroxaban and its safety when used by patients for the prevention of artherothrombotic (plaque rupture leading to a blood clot) events following ACS, during the first three months after starting. This study was requested by the European regulatory body (EMA) which is responsible for the use and safety of medicines. It will last for approximately 3 years and is a national study covering the whole of England and Wales. The study aims to recruit 1193 patients who have been prescribed rivaroxaban and antiplatelet therapy and 1193 patients who have been prescribed alternative dual antiplatelet therapy for the secondary prevention of artherothrombotic events following ACS. Each patient will only be monitored for the first 13 weeks after hospital admission for ACS. Patients who choose to take part will complete a consent form. The patient's care team will be asked to complete a baseline questionnaire about the patient at the time the medicine is given and a further questionnaire up to 16 weeks later, specifically asking about the patient's experiences whilst on the medication. If anything unusual is reported during the observation period, the care team may be asked to fill out a followup questionnaire. With the patient's consent, the study team will also inform the patient's GP of their participation in the study and will ask the GP to complete an abridged questionnaire from the patient's medical records. The study team will analyse and aggregate the data, carefully protecting patient confidentiality, to classify adverse events of interest, in

particular bleeding events.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### Drug Safety Research Unit (DSRU)

 United Kingdom

**First published:** 10/11/2021

**Last updated:** 09/01/2026

**Institution**

**Not-for-profit**

**ENCePP partner**

### Networks

#### NIHR Medicines for Children Research Network

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

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

**Network**

### Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Saad Shakir

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 02/06/2014

Actual: 02/06/2015

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**Study start date**

Planned: 01/09/2015

Actual: 01/09/2015

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**Date of interim report, if expected**

Planned: 30/09/2017

Actual: 27/10/2017

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**Date of final study report**

Planned: 31/10/2019

Actual: 30/10/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer Pharma AG

## Study protocol

[ACS SCEM Final\\_30\\_08\\_2017\\_version 7\\_Clean.pdf](#) (846.95 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:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

1. To quantify the cumulative incidence (risk and rate) of haemorrhage (major bleeding within intracranial, gastrointestinal and urogenital organ sites) occurring in the 12 week observation period

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

RIVAROXABAN

## Population studied

**Short description of the study population**

Patients in the secondary care hospital setting in England and Wales.

This study will be a prospective observational, population-based cohort study of rivaroxaban with a contextual comparator (reference cohort). The rivaroxaban cohort consists of new rivaroxaban users (no anticoagulant prescription within 6 months prior to index date) with any combination of oral antiplatelet therapy for the prevention of atherothrombotic events following ACS. The contextual cohort consists of patients receiving the current standard treatment of care for the prevention of atherothrombotic events following an ACS (at least dual antiplatelet therapy, but not monotherapy).

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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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### **Estimated number of subjects**

2386

## **Study design details**

### **Outcomes**

Intracranial, gastrointestinal or urogenital major bleeding.

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### **Data analysis plan**

- quantify the cumulative incidence (risk and rate) of major bleeding -  
descriptive exploratory analysis of patient population prescribed rivaroxaban-  
quantify the risk of other major (in any other site not specified in the primary objective) or minor bleeding outcomes (in any site) reported in the 12 week

observation period overall

## Documents

### Study results

[17542\\_EU PAS Abstract\\_Redacted\\_V1.0\\_2019-11-21.pdf](#) (296.37 KB)

[DSRU SCEM ACS - Abstract Final Report.pdf](#) (125.94 KB)

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### Study report

[17542\\_Clinical Study Report\\_Redacted\\_V1.0\\_2019-11-21.pdf](#) (8.37 MB)

[DSRU EUPAS9977 - Summary Interim Report\\_3Feb2019.pdf](#) (86.12 KB)

### Study, other information

[DSRU EUPAS9977 - Summary Interim Report\\_3Feb2019.pdf](#) (86.12 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 sources (types)

[Other](#)

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### **Data sources (types), other**

Study questionnaires will be completed using data from patient medical records.

## 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