Xarelto (Rivaroxaban) Risk Minimisation Plan Evaluation: Patient and Physician Knowledge of Key Safety Messages

First published: 12/06/2013

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/40441

EU PAS number

EUPAS3911

Study ID

40441

DARWIN EU® study

No

Study countries

☐ France

- [ ] Germany
- [ ] Spain
- [ ] United Kingdom

Study description

This cross-sectional epidemiologic study will measure physician and patient awareness and understanding of the key messages in the Xarelto prescriber guide and Xarelto patient alert card.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution **Not-for-profit** **ENCePP partner**

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

Elizabeth B. Andrews

Study contact

eandrews@rti.org

Primary lead investigator

Elizabeth B. Andrews

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/12/2011

Study start date

Planned: 15/09/2014

Actual: 15/09/2014

Date of final study report

Planned: 10/06/2020

Actual: 18/06/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

16167_Xarelto_Protocol_Risk Minimization Study_Final_28Nov2011.pdf(1.66 MB)

16167_Protocol_V4_Wave II_redacted.pdf(1.69 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

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

Data collection methods:

Primary data collection

Main study objective:

The main objective of this cross-sectional epidemiologic study is to measure physician and patient awareness and understanding of the key messages in the prescriber guide and patient alert card.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

Anticoagulant therapy

Population studied

Short description of the study population

Physicians and patients with recent rivaroxaban experience.
Physicians were eligible to participate if they had prescribed rivaroxaban in the past 6 months for one of the indications of interest.
Patients were eligible if they had taken rivaroxaban within the last 3 months for one of the indications of interest.

Patients will be identified through selection of a diverse set of medical practices across the five targeted countries. To be eligible for the study, the patients must meet all of the following criteria:
1. Patient has taken rivaroxaban within the last 3 months for prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation (SPAF) or treatment of DVT and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults.
2. Patient is aged 18 years or older.
3. Patient is able to understand and complete the consent form and patient questionnaire.
4. Patient can read and understand the native language of the country in which the study is being conducted.
5. Patient has not participated in a clinical trial for a treatment to prevent blood clots in the past 12 months.

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)

Estimated number of subjects

5000

Study design details

Outcomes

1) Knowledge and understanding among physicians regarding key safety information contained in the prescriber guide assessed by web-based questionnaire.2) Knowledge and understanding of patients regarding the key safety information contained in the patient alert card assessed by paper-based questionnaire.

Data analysis plan

Analyses will include detailed review of responses to individual questions as well as potential summary measure across logical grouping of response items. Physician results will bestratified by country, speciality, and other logical variables. Patient results will be stratified by country and other logical variables, potentially including a measure of the knowledgelevel of their physician. A detailed analysis plan describing methods of analysis and presentation, as well as table shells, will be developed prior to starting analysis of data.

Documents

Study results

16167_EU PAS Abstract_Redacted_V 1.0_2020-06-09.pdf(223.79 KB)

Study report

16167_Clinical Study Report_Wave III_redacted_V 1.0_2020-06-09.pdf(1.94 MB)

16167_Clinical Study Report_Wave II_redacted_V 1.0_ 2018-05-24.pdf(3.67 MB)

16167_Clinical Study Report_Wave I_redacted_V 1.0_2015-10-16.pdf(9.48 MB)

16167_progress report.pdf(119.93 KB)

RTI EUPAS3911 - Summary Interim Report.pdf(88.78 KB)

Study, other information

16167_Protocol_V2_Wave I_redacted.pdf(4.07 MB)

16167_Clinical Study Report_Wave II_redacted_V 1.0_ 2018-05-24.pdf(3.67 MB)

16167_Clinical Study Report_Wave I_redacted_V 1.0_2015-10-16.pdf(9.48 MB)

16167_progress report.pdf(119.93 KB)

RTI EUPAS3911 - Summary Interim Report.pdf(88.78 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Cross-sectional survey to patients and physicians

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