Post-authorisation study to evaluate the effectiveness of the risk minimisation activities in the treatment of SPAF (Risk minimisation in SPAF)

First published: 27/03/2015

Last updated: 30/03/2016

Study Finalised

Administrative details

EU PAS number

EUPAS9111

Study ID

12992

DARWIN EU® study

No

Study countries

Bulgaria

Czechia

Denmark

France
Germany
Slovakia
Spain
United Kingdom

Study description

The objective of the investigation is evaluate the effectiveness of the risk minimisation activities in the treatment of stroke prevention in atrial fibrillation.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 400 centres are involved in the study

Contact details

Study institution contact

Martin Feuring martin.feuring@boehringer-ingelheim.com

Study contact

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Primary lead investigator

Martin Feuring

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/11/2012

Actual: 25/06/2014

Study start date

Planned: 01/10/2012

Actual: 15/01/2015

Data analysis start date

Planned: 01/10/2012

Actual: 15/01/2015

Date of final study report

Planned: 31/08/2015

Actual: 12/02/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Pharma

Regulatory

Was the study required by a regulatory body?

Yes

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Other

Study topic, other:

Disease/Epidemiology study

Study type:

Not applicable

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Other

If ‘other’, further details on the scope of the study

Risk awareness

Data collection methods:

Primary data collection

Main study objective:

The key focus of this survey will be to collect data on physicians’ awareness of the content of the Pradaxa® Prescriber Guide and the extent to which risk awareness is communicated to patients. The data collected with AF patients will show if and how well this information isreceived and understood.

Study drug and medical condition

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Physicians: Current prescribers of Pradaxa® for stroke prevention in patients with atrial fibrillation (AF).

Patients: Atrial fibrillation (AF) patients on treatment with Pradaxa®.

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)

Special population of interest

Other

Special population of interest, other

Patients with atrial fibrillation

Estimated number of subjects

1200

Study design details

Outcomes

Physician’s knowledge and recommendations to their patients onappropriate dosing and minimizing the risk of bleeding whentreated with Pradaxa®. Patients’ understanding of the disease, bleeding signs, what to do in case of bleeding and how to deal with emergency situations

Data analysis plan

Descriptive Statistics:For both Physician and Patient Surveys, all estimates of proportions andmeans will be presented for the following groups: the entire populations for physicians and for patients, stratified by country.

Documents

Study results

1160-0149_Post Authorisation Study_marked_Redacted.pdf (878.21 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

Data sources (types), other

Physician’s knowledge and recommendations to their patients on appropriate dosing and minimizing the risk of bleeding when treated with Pradaxa®
Patients’ understanding of the disease, bleeding signs, what to do in case of bleeding and how to deal with emergency situations.

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