Post-Marketing Surveillance on the Use of Prazaxa® (Japanese Prazaxa PMS, second)

First published: 25/05/2017

Last updated: 25/09/2026

Study Finalised

Administrative details

EU PAS number

EUPAS19283

Study ID

43885

DARWIN EU® study

No

Study countries

Japan

Study description

The study objective is to confirm appropriate use and safety profile of Prazaxa® Capsules in real-world setting after the availability of idarucizumab.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 800 centres are involved in the study

Contact details

Study institution contact

Tanaka Katsumi zzCDMJP_PV_PMS@boehringer-ingelheim.com

Study contact

zzCDMJP_PV_PMS@boehringer-ingelheim.com

Primary lead investigator

Tanaka Katsumi

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/03/2017

Study start date
Actual: 26/07/2017

Data analysis start date
Actual: 14/04/2021

Date of final study report
Actual: 13/10/2021

Sources of funding

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.,

Study protocol

1160-0284_CTP_final-rule_Redacted.pdf (319.55 KB)

1160-0284_protocol_redacted.pdf (319.55 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Other study registration identification numbers and links

1160-0284

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The study objective is to confirm appropriate use and safety profile of Prazaxa® Capsules in real-world setting after the availability of idarucizumab.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-interventional, prospective, observational, single arm

Study drug and medical condition

Medicinal product name

PRADAXA

Medicinal product name, other

Prazaxa Capsules 75 mg 110 mg

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

DABIGATRAN ETEXILATE

Anatomical Therapeutic Chemical (ATC) code

(B01AE07) dabigatran etexilate

dabigatran etexilate

Medical condition to be studied

Atrial fibrillation

Population studied

Short description of the study population

Adolescents and adults using Prazaxa® Capsules in real-world setting after the availability of idarucizumab.

Age groups

- 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

6.000

Study design details

Outcomes

Primary outcome:

Absolute and relative (%) frequency of patients with suspected adverse drug reactions (ADRs).

Secondary outcome

None

Further outcomes:

Incidence of stroke/SEE

Incidence of bleeding

Incidence of myocardial infarction (MI)

Incidence of gastrointestinal (GI) disorder

Data analysis plan

Analyses are descriptive in nature, including confidence intervals. Due to the nature of the observational study, no confirmatory statistical testing is foreseen in this study. Subgroup analyses are also performed if sample size allows.

Documents

Study results

1160-0284_Synopsis.pdf (518.88 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 source(s), other

Patients' data was collected by electronic Case Report Form (eCRF) on Electronic Data Capture (EDC) system

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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