Post marketing surveillance program of PraxbindTM use in (PraxbindTM India PMS program)

First published: 10/11/2017

Last updated: 21/10/2026

Study Finalised

Administrative details

EU PAS number

EUPAS21619

Study ID

34131

DARWIN EU® study

No

Study countries

India

Study description

The main objective of the PraxbindTM administration surveillance program is to evaluate the prescription patterns of use of PraxbindTM in a clinical practice setting, with special focus on ADRs and fatal AEs. Primary Outcome:-Any suspected ADRs and fatal AEs, with special focus on hypersensitivity and thrombotic event, occurred within 7 days after PraxbindTM administration.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

AIIMS New Delhi, Sir HN Reliance Foundation Hospiat Mumbai, Dr L H Hiranandani Hospital Mumbai, St. John's Medical College and Hospital Bengaluru, Apollo Hospital Chennai, Medanta, The Medicity New Delhi, Batra Hospital and Medical Research Centre New Delhi, Sir Ganga Ram

Hospital New Delhi, Holy Family hospital Mumbai, Nizams Institute of Medical Sciences Hyderabad

Contact details

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Study contact

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Primary lead investigator

Bondal Sumedh

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/07/2017

Actual: 19/07/2017

Study start date

Planned: 20/12/2018

Data analysis start date

Planned: 19/03/2020

Date of final study report

Planned: 20/04/2020

Actual: 06/10/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim India Pvt. Ltd.

Study protocol

1321-0023_CTP_final-rule_Redacted.pdf (889.09 KB)

non-interventional-study-protocol-version-03.pdf (471.12 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

1321-0023

NCT03359889

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Multicenter, non-interventional, drug administration surveillance program

Main study objective:

The main objective of the PraxbindTM drug administrationsurveillance program is to evaluate the prescription patterns of useof PraxbindTM in a clinical practice setting, with special focus onADRs and fatal AEs.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post Marketing Surveillance

Study drug and medical condition

Medicinal product name

PRAXBIND

Medicinal product name, other

PraxbindTM

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

IDARUCIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(V03AB37) idarucizumab

idarucizumab

Medical condition to be studied

Brief resolved unexplained event

Population studied

Short description of the study population

1. Patients treated with Pradaxa® (dabigatran etexilate) capsules with requirement of rapid reversal of the anticoagulant effects of dabigatran:

- For emergency surgery/urgent procedures

Or

- In life-threatening or uncontrolled bleeding

2. Written informed consent in accordance with International Conference on Harmonization Good Clinical Practice (GCP) guidelines and local legislation and/or regulations.

Exclusion criteria:

- Participation in a Praxbind® clinical trial

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

25

Study design details

Setting

The study was performed in the Clinical Practice Setting. Participating hospitals had readiness for emergency services and access to Praxbind®.

Outcomes

Primary outcomesAny suspected ADRs and fatal AEs, with special focus on hypersensitivity and thrombotic event, occurred within 7 days after PraxbindTM administration. Secondary outcomesPercentage of patients who either received PraxbindTM for emergency surgery/urgent procedures or in life-threatening or uncontrolled bleeding at the end of 2 years.

Data analysis plan

All variables will be presented using descriptive statistics (absolute and relative frequencies, means, standard deviations, medians, quartiles, minimum and maximum values, 95% CIs) as appropriate for the nature of the variables (i.e. categorical or continuous).

Summary results

Discussion: Praxbind® was used according to the approved label and all patients received Pradaxa® prior to initiation of Praxbind®. Due to the small overall size of the study and the low numbers of patients, this may not represent the general usage of Praxbind® in India.In this post-marketing surveillance study, five patients with life-threatening or uncontrolled bleeding or requiring urgent procedure were treated with Praxbind®. Bleeding had ceased in three patients, in one patient, the bleeding status was not known at the time of last reporting but this patient was hemodynamically stable after use of Praxbind®.One patient received study drug for reversal before initiating thrombolysis for acute ischemic stroke (an urgent procedure) treatment and found to be stable after medical treatment. No deaths, suspected ADR (serious or non-serious) or hypersensitivity or thrombotic AEs were reported in the study.

Documents

Abstract of study report

1321-0023_Synopsis.pdf (249.37 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

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