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

First published: 10/11/2017

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Administrative details

| EU PAS number | |
|------------------|--|
| EUPAS21619 | |
| Study ID | |
| 34131 | |
| DARWIN EU® study | |
| No | |
| Study countries | |
| India | |

Study description

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

Study status

Planned

Research institutions and networks

Institutions

Boehringer Ingelheim

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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

Study institution contact

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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

Sources of funding

• Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim India Pvt. Ltd.

Study protocol

clinical-trial-protocol-version-02.pdf (462.77 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

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

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

Name of medicine, other

PraxbindTM

Medical condition to be studied

Brief resolved unexplained event

Population studied

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

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% Cls) as appropriate for the nature of the variables (i.e. categorical or continuous).

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