The drug use-results survey (All-Case Surveillance) on Prizbind® for Intravenous Solution 2.5 g in Japan (PMS for idarucizumab)

First published: 27/10/2016

Last updated: 30/08/2022

Study Finalised

Administrative details

EU PAS number

EUPAS15981

Study ID

48788

DARWIN EU® study

No

Study countries

☐ Japan

Study description

Study to evaluate safety and effectiveness of Prizbind® for Intravenous Solution 2.5 g under Japanese clinical condition

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Multiple centres: 300 centres are involved in the study

Contact details

Study institution contact

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Study contact

zzCDMJP_PV_PMS@boehringer-ingelheim.com

Primary lead investigator

Yukako Ogi

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/08/2016

Actual: 19/08/2016

Study start date

Planned: 27/10/2016

Actual: 25/11/2016

Data analysis start date

Planned: 01/11/2016

Actual: 25/11/2016

Date of interim report, if expected

Planned: 03/11/2021

Actual: 24/09/2021

Date of final study report

Planned: 31/07/2022

Actual: 17/08/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Nippon Boehringer Ingelheim Co., Ltd.

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Study to to evaluate safety and effectiveness of Prizbind® for Intravenous Solution 2.5 g under Japanese clinical condition

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Upper gastrointestinal haemorrhage

Population studied

Short description of the study population

Japanese subjects with upper gastrointestinal haemorrhage treated with Prizbind (Intravenous Solution 2.5 g) under clinical condition.

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

300

Study design details

Outcomes

Any suspected ADRs (primary outcome), Serious AEs, and AEs for important potential risks(hypersensitivity, thrombotic event), Reversal of anticoagulation as measured by coagulation test

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Data analysis plan

Analyses are descriptive in nature including means, standard deviation, min, Q1, medians, Q3, max, frequency and percentages

Data management

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