# 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

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## Administrative details

**Study description** 

<b>EU PAS number</b> EUPAS15981	
<b>Study ID</b> 48788	
DARWIN EU® study	
Study countries  Japan	

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**

Yukako Ogi zzCDMJP\_PV\_PMS@boehringer-ingelheim.com

Study contact

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#### **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

#### Data analysis plan

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

## 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

Other	(types)				
Data sources	(types), othe	r			
Prospective pa	ient-based dat	a collectio	n		
Use of a (	Common	Data N	Model (	CDM)	
CDM mapping					
No					
Data qua	ity spacit	fication	2.5		
Data qua	ity specii	icatioi	15		
Check confor		icatioi	15		
•		icatioi	15		
Check confor	nance	icatioi	15		
Check confor	nance	icatioi	15		
Check conford Unknown Check comple	nance teness	icatioi	15		

# Data characterisation

## **Data characterisation conducted**

No