Safety of potential paediatric patients treated by idarucizumab: a worldwide non-interventional chart review study (Pediatric NIS)

First published: 13/04/2018

Last updated: 17/12/2025

Study Cancelled

Administrative details

EU PAS number

EUPAS23589

Study ID

27019

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Canada
- [ ] Germany

☐ United Kingdom

☐ United States

Study description

This paediatric non-interventional study is designed as a global multi-national multi-centre study based on medical charts. Sites with potential paediatric use of idarucizumab will be identified by various methods (eg. idarucizumab drug administrion surveillance program, spontaneous reporting).

Study status

Cancelled

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 03/12/2014

Study start date
Planned: 31/01/2019

Date of final study report
Planned: 31/10/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

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

Main study objective:

• To characterize potential paediatric patients administered with idarucizumab

• To further collect safety data among the paediatric patients until hospital discharge:

o Incidence of thromboembolic events after administrationo

o Incidence of hypersensitivity / anaphylactic reactionso

o Incidence of Adverse Events (AE), Serious Adverse Ev

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Non-interventional study based on medical chart review

Study drug and medical condition

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

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

10

Study design details

Outcomes

Based on observed events until observation discharge:

- thromboembolic events (incidence rate)
- hypersensitivity / anaphylactic reactions (incidence rate)
- AE, SAE, ADR, SADR reporting (incidence rates)
- in-hospital death (incidence rate, cause of death),

Comparison of patient characteristics of paediatric patients with and without primary outcome events.

Data analysis plan

Patients will be analysed separately based on the methods by which the idarucizumab usage was identified (eg. Idarucizumab drug administration surveillance program, spontaneous reporting). As this is a descriptive study, no hypotheses will be tested, all variables will be presented using descriptive statistics, incidences rates for the outcome events and 95% confidence intervals. Patients' characteristics will be described for patients with and without outcome events.

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

Medical Chart review

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