Thromboembolic events reported in association with idarucizumab and andexanet alfa: disproportionality analysis of the Food and Drugs Administration Adverse Eventr Resporting System (FAERS) database (Idarucizumab/andexanet alfa & thromboembolism)

First published: 24/10/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS107330

Study ID

108399

DARWIN EU® study

No

Study countries

Italy

Study description

Idarucizumab and andexanet alfa are drugs for the emergency reversal of pharmacological effect of direct oral anticoagulant (DOAC) drugs. However, given the recent commercialization of these two antidotes (2015 for idarucizumab, 2018 for andexanet) and their rare use in clinical practice, evidence on the safety of idarucizumab regarding thromboembolic risk is still limited. The aim of this study is to analyze the Food and Drugs Administration Spontenouse Reporting System (FAERS) database for generating hypothesis on the possible association between the use of idarucizumab and specific thromboembolic events, which can be subsequently verified through ad hoc observational studies.

Study status

Ongoing

Research institutions and networks

Institutions

Agenzia regionale di sanità della Toscana (ARS)

Italy

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Institution | EU Institution/Body/Agency | ENCePP partner

Contact details

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Study contact

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Primary lead investigator

Roberto Giuseppe

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 25/08/2023

Study start date

Actual: 02/10/2023

Date of final study report

Planned: 30/11/2024

Sources of funding

- Other

More details on funding

ARS

Study protocol

Idarucizumab_andexanet alfa_thromboebolic events_FAERS_v01_ENCEPP.pdf
(937.54 KB)

Idarucizumab_andexanet alfa_thromboebolic events_FAERS_v01_1_ENCEPP.pdf
(940.16 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

Generate hypotheses regarding the possible association between the use of idarucizumab and specific thromboembolic events, which can be subsequently verified through ad hoc observational studies.

Study Design

Non-interventional study design

Other

Study drug and medical condition

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

IDARUCIZUMAB

ANDEXANET ALFA

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

11000000

Study design details

Data analysis plan

Using all reports of suspected adverse drug reactions in the database, the Reporting Odds Ratios will be calculated, with 95% confidence intervals, for idarucizumab and andexanet alfa, respectively, in association with the three relevant SMQs and subsequently in association with each of the PTs contained

within each of the three SMQ. Drug-event pairs with ROR>1 and at least 3 reports will be considered as signals of disproportionate reporting. As a sensitivity analysis, the analysis will be restricted to reports concerning any DOAC (i.e. dabigatran, rivaroxaban, apixaban, edoxaban) among suspected, interacting or concomitant drug and at least one among idarucizumab, andexanet alfa or a prothrombin complex concentrate, i.e. the therapeutic alternative to idarucizumab, andexanet alfa, listed as suspected or interacting drug.

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 source(s), other

FAERS United States

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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