Severe hypersensitivity reactions associated with high dose iv iron containing medicinal products

First published: 08/08/2018

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS25192

Study ID

28647

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Bulgaria
- Croatia

- Czechia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Netherlands
- Norway
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- United Kingdom

Study description

Evaluation of severe hypersensitivity reactions after administration of high dose iv irons with respect to overall exposure in European countries by using information from existing data sources

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Gohlke Annegret

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 08/03/2018

Study start date

Planned: 15/06/2018

Actual: 02/07/2018

Data analysis start date

Planned: 02/07/2018

Actual: 16/07/2018

Date of final study report

Planned: 31/12/2018

Actual: 12/02/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Vifor International AG

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Case-population study

Data collection methods:

Secondary use of data

Main study objective:

To evaluate the reported rate of anaphylactic/anaphylactoid reactions associated with single high dose IV iron products with respect to overall exposure of single iron products in European countries, including:ferric carboxymaltose and iron isomaltoside

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Pharmacoepidemiologic study with case-population design using established data sources

Study drug and medical condition

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

FERRIC CARBOXYMALTOSE

IRON(III) ISOMALTOSIDE 1000

Medical condition to be studied

Anaphylactoid shock

Anaphylactic reaction

Population studied

Short description of the study population

Patients with an injection or infusion of ferric carboxymaltose or iron (III) isomaltoside 1000 s in the inpatient and outpatient setting in European countries.

Age groups

- Adolescents (12 to < 18 years)
- 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

99999999

Study design details

Data analysis plan

In a descriptive analysis reported rates of severe hypersensitivity AEs including anaphylactic reaction, anaphylactic shock, anaphylactoid reaction and anaphylactoid shock for the period 1 Jan 2014 – 31 Dec 2017 will be determined by number of reports divided by the number of 100 mg DEq (=DDD) of iron sold.Odds Ratios and corresponding 95 % CI will be calculated.

Documents

Study results

201902012_PASS_Report_Severe HSR_Vifor Pharma_Final_2.0_Abstract.pdf (94.52 KB)

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

EudraVigilance

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Vigibase: WHO Program for International Drug Monitoring database for AE reporting IQVIA (IMS) sales data: volume of drugs in retail and hospital setting in European countries

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

Unknown