Severe hypersensitivity reactions associated with i.v. iron containing medicinal products in countries of the European Economic Area – before and after implementation of risk minimisation measures

First published: 09/02/2019

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS27963

Study ID

30103

DARWIN EU® study

No

Study countries

Austria
Belgium
Bulgaria
Croatia
Czechia
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Iceland
Ireland
Italy
Latvia
Lithuania
Netherlands
Norway
Poland
Portugal
Romania
Slovakia
Spain
Sweden
United Kingdom

Study description

Evaluation of the reported rate of severe hypersensitivity reactions after administration of iv irons with respect to overall exposure in countries of the

European Economic Area by using information from existing data sources

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

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Institution | **Non-Pharmaceutical company** | **ENCePP partner**

N/A

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: 06/11/2018

Study start date
Planned: 26/11/2018

Actual: 26/11/2018

Data analysis start date
Planned: 07/12/2018

Actual: 17/12/2018

Date of final study report
Planned: 15/02/2019

Actual: 19/02/2019

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:

Human medicinal product

Disease /health condition

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 overall and substance-specific reporting rate of anaphylactic/anaphylactoid reactions associated with i.v. iron-containing substances with respect to overall exposure of each i.v. iron substance in EEA countries for the 4-year period preceding the implementation of risk minimization measures (2010-2013) and the 4-year period after the implementation (2014-2017)

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This is a pharmacoepidemiologic study with case-population design using established data sources.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B03AC) Iron, parenteral preparations

Iron, parenteral preparations

Medical condition to be studied

Anaphylactoid shock

Anaphylactic reaction

Population studied

Short description of the study population

All available records of anaphylactic reactions and anaphylactoid reactions associated with ferric carboxymaltose, iron sucrose, iron (III) isomaltoside 1000, iron dextran, iron gluconate/ferric gluconate or ferumoxytol in EEA countries in the time period 1 January 2010 to 31 December 2017 in EudraVigilance were considered for the analysis.

Age groups

- Children (2 to < 12 years)
- 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 reporting rates of severe hypersensitivity reactions defined as anaphylactic reaction, anaphylactic shock, anaphylactoid reaction and anaphylactoid shock will be determined by number of reports divided by the number of 100 mg dose equivalents (DEq, =DDD) of iron sold.

Documents

Study results

20190611_PASS_Report_Severe HSR_2010-2017_Vifor Pharma_Abstract_clean.pdf (62.83 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)

Other

Data sources (types), other

Sales data for drugs 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

No