

# 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

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### Study ID

28647

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### DARWIN EU® study


No

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### 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
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## **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

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## **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

Birgit Ehlken [behlken@de.imshealth.com](mailto:behlken@de.imshealth.com)

Study contact

[behlken@de.imshealth.com](mailto:behlken@de.imshealth.com)

### Primary lead investigator

Gohlke Annegret

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 08/03/2018

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### Study start date

Planned: 15/06/2018

Actual: 02/07/2018

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### **Data analysis start date**

Planned: 02/07/2018

Actual: 16/07/2018

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### **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

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### **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

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**Study type:**

Non-interventional study

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**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

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**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

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**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

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### **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.

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### **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)
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### **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)

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## 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

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### Data sources (types)

Administrative healthcare records (e.g., claims)

Other

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### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

## **Data characterisation conducted**

Unknown