Ferumoxytol-5005: Hypersensitivity events occurring proximal to administration of intravenous iron

First published: 06/10/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS15737

Study ID

44009

DARWIN EU® study

No

Study countries

United States

Study description

The purpose of this study was to assess incidence of hypersensitivity events and mortality proximal to intravenous (IV) iron use. This was assessed among a 2010 and 2011 US: 1) Dialysis population using CMS end-stage renal disease (ESRD) data, and 2) Non-dialysis chronic kidney disease (CKD) and non-CKD population using Medicare 20% sample data. Incidence of hypersensitivity and mortality rates were reported by IV iron type (InFed, Ferrlecit, Venofer, and Feraheme).

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Stephan Dunning

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 08/04/2014

Study start date

Actual: 16/04/2014

Data analysis start date
Actual: 30/04/2014

Date of final study report
Actual: 17/06/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Takeda Development Centre

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:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To assess incidence of hypersensitivity events, and all-cause mortality rates proximal to intravenous (IV) iron administration, overall and by type of IV iron.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

IRON SUCROSE

Medical condition to be studied

Iron deficiency anaemia

Population studied

Short description of the study population

1) Dialysis population using CMS end-stage renal disease (ESRD) data, and 2) Non-dialysis chronic kidney disease (CKD) and non-CKD population using Medicare 20% sample data.

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)

Special population of interest

Renal impaired

Estimated number of subjects

693999

Study design details

Outcomes

To assess hypersensitivity/hypotension adverse events, including death, proximal to IV iron administration in 2010 and 2011 dialysis patients,

nondialysis CKD patients, and non-CKD patients a. Overall, b. By IV iron type, and c. By age and sex. To describe patient characteristics and frequency of IV iron use in 2010 and 2011 dialysis patients, nondialysis CKD patients, and non-CKD patients.

Data analysis plan

Analyses were carried out at the event level (IV iron administration level). Hypersensitivity events: Annual incidence (per 100,000 IV iron administrations) of hypersensitivity events occurring on the day of/day after IV iron administration was calculated. Mortality: Deaths occurring in the seven days following IV iron administration were captured to calculate age-standardised mortality rates (ASMRs). The above incidence and ASMR estimates were reported 1) overall, 2) by IV iron type, 3) by gender and age-group, and were stratified by indication (i.e. CKD (dialysis and nondialysis), and non-CKD).

Documents

Study results

Ferumoxytol-RDS-2016-02-09.pdf (81.35 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 sources (types)

Administrative healthcare records (e.g., claims)

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