

Non-interventional Post Authorization Safety Study (PASS) to evaluate hypersensitivity reactions associated with administration of intravenous iron sucrose in Chronic Kidney Disease (CKD) patients, under dialysis or not

First published: 16/12/2016

Last updated: 02/04/2024

Study

Planned

Administrative details

EU PAS number

EUPAS16600

Study ID

18174

DARWIN EU® study

No

Study countries

Study status

Planned

Research institutions and networks

Institutions

Phaze Clinical Research and Pharma Consulting

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Spyridon Anagnostopoulos

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/04/2016

Study start date

Planned: 31/03/2017

Date of final study report

Planned: 01/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Cooper A.E., Demo A.B.E.E., Help ABEE, Propius P.C., Target Pharma ΜΕΠΕ, UNI-PHARMA ΚΛΕΩΝ ΤΣΕΤΗΣ ΦΑΡΜΑΚΕΥΤΙΚΑ ΕΡΓΑΣΤΗΡΙΑ ABEE

Study protocol

[CTP - IRON GR-001_21Nov16.pdf](#) (619.42 KB)

[CTP - IRON GR-001_v2.0 _21Nov16 final.pdf](#) (6.13 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective is to assess the proportion of hypersensitivity reactions after administration of IV iron sucrose in CKD patients, under dialysis or not as per standard clinical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Intensive monitoring schemes, Active surveillance

Study drug and medical condition

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

IRON SUCROSE

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)
-

Special population of interest

Renal impaired

Estimated number of subjects

570

Study design details

Data analysis plan

The primary safety analysis will examine the frequency and percentage of patients experiencing hypersensitivity reactions, serious adverse events and adverse events associated with IV iron sucrose treatment. The adverse events will be coded using MedDRA (Medical Dictionary for Regulatory Activities) and tabulated by seriousness, system organ class and preferred term. The adverse event rates will be computed for all study patients combined as well as for subgroups of patients of particular interest.

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)

Other

Data sources (types), other

Prospective patient-based data collection

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