A non-interventional study of Diafer® (5% Iron Isomaltoside 1000) administered according to standard hospital practice and product labelling in subjects with Chronic Kidney Disease on Haemodialysis for treatment of iron deficiency (Diafer-NIS-06)

First published: 07/07/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28188

EU PAS number

EUPAS7008

Study ID

28188

DARWIN EU® study

No

Study countries

- [ ] Sweden
- [ ] United Kingdom

Study description

A prospective 12 months multicentre observational study with systematic monitoring of anaemia-related parameters and safety in relation to intravenous Diafer® therapy according to local clinic standards. The primary objective of the study is to monitor initiated Diafer® therapy administered according to hospital practice and the product labelling in routine clinical practice in haemodialysis patients with chronic kidney disease. The primary efficacy outcome is haemoglobin concentration compared to baseline and key secondary endpoints include iron dose, erythropoietin-stimulating agent dose, and haematinics. Safety will be evaluated by the number and seriousness of adverse drug reactions and adverse events of special interest.

Study status

Finalised

Research institutions and networks

Institutions

Diaverum, Heleneholmsdialysen

Sahlgrenska University Hospital Gothenburg, Sweden, Morriston Hospital Swansea, Wales, UK, Royal Devon&Exeter Hospital Exeter, Devon, UK, Norrland University Hospital Umeå, Sweden

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Staffan Schön

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/02/2014

Actual: 07/02/2014

Study start date

Planned: 01/09/2014

Actual: 23/08/2014

Date of final study report
Planned: 15/02/2017

Actual: 28/11/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pharmacosmos A/S

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

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of the study is to monitor initiated Diafer® therapy administered according to hospital practice and the product labelling in routine clinical practice in haemodialysis patients with chronic kidney disease.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B03A) IRON PREPARATIONS

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Medical condition to be studied

Haemodialysis

Population studied

Short description of the study population

Patients ≥ 18 years of age and in a stable phase of chronic kidney disease (CKD), had been on haemodialysis (HD) therapy > 3 months, and had received at least one dose of iron sucrose (IS) treatment within the last 6 months before study start while being on HD.

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

200

Study design details

Outcomes

The primary efficacy outcome is haemoglobin concentration compared to baseline. Key secondary endpoints include iron dose, erythropoietin-stimulating agent dose, haematinics and safety.

Data analysis plan

The data will be displayed by descriptive statistics and by comparing results from the patients to historical data from the same patients.

Documents

Study publications

Mikhail AI, Schön S, Simon S, Brown C, Hegbrant JB, Jensen G, Moore J, Lundberg…

Data management

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

Unknown