

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

### EU PAS number

EUPAS7008

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### Study ID

28188

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### DARWIN EU® study

No

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### Study countries

 Sweden

 United Kingdom

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### **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.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

[Diaverum, Heleneholmsdialysen](#)

[Sahlgrenska University Hospital Gothenburg, Sweden, Morrison Hospital Swansea, Wales, UK, Royal Devon&Exeter Hospital Exeter, Devon, UK,](#)

## Contact details

### Study institution contact

Sylvia Simon [ssi@pharmacosmos.com](mailto:ssi@pharmacosmos.com)

Study contact

[ssi@pharmacosmos.com](mailto:ssi@pharmacosmos.com)

### Primary lead investigator

Staffan Schön

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 07/02/2014

Actual: 07/02/2014

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### Study start date

Planned: 01/09/2014

Actual: 23/08/2014

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### 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

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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:**

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

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**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

IRON PREPARATIONS

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**Medical condition to be studied**

Haemodialysis

## Population studied

**Short description of the study population**

Patients  $\geq$  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.

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## 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)
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## Special population of interest

Renal impaired

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## 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.

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## 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...](#)

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## Data management

ENCePP Cool

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

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### 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

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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