

# A non-intervention trial of the time to relapse of iron deficiency anemia after standard treatment with a new intravenous iron (Monofer®) (Monofer®-NIS-14)

**First published:** 08/08/2013

**Last updated:** 15/02/2019

Study

Finalised

## Administrative details

### EU PAS number

EUPAS4492

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### Study ID

28191

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### DARWIN EU® study

No

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### Study countries

☐ Denmark

☐ Norway

☐ Sweden

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## Study description

A prospective Scandinavian multicentre non-intervention trial with systematic monitoring of iron parameters in relation to intravenous iron isomaltoside 1000 (Monofer®) therapy according to local hospital standards.

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## Study status

Finalised

## Research institutions and networks

### Institutions

NA

Multiple centres: 16 centres are involved in the study

## 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

Tor Melin

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Actual: 06/08/2013

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### **Study start date**

Planned: 13/09/2013

Actual: 19/08/2013

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### **Date of final study report**

Planned: 17/06/2016

Actual: 18/07/2018

## 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:**

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:**

Primary data collection

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#### **Main study objective:**

The objective is to monitor and quality assure the efficacy and safety of Monofer® in a broad patient population when Monofer® is used according to the Monofer® label (SPC) in current practice and where standard routines are being followed.

### Study drug and medical condition

## Medicinal product name, other

Monofer

## Population studied

### Short description of the study population

Participants aged > 17 years and diagnosed with iron deficiency anaemia following local clinical guidelines.

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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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### Estimated number of subjects

400

## Study design details

### Outcomes

The primary endpoint is time to relapse of iron deficiency anemia and need of a new course of Monofer® treatment. Laboratory assessments, i.e. anemia work-up/treatment evaluation

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### Data analysis plan

The data will be analysed by descriptive statistics.

## Documents

## Study publications

Frigstad SO, Haaber A, Bajor A, Fallingborg J, Hammarlund P, Bonderup OK, Blom ...

Jensen G, Gøransson LG, Fernström A, Furuland H, Christensen JH. Treatment of i...

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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 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**

No