# 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

**Study ID**

28191

**DARWIN EU® study**

No

**Study countries**

- [ ] Denmark
- [ ] Norway
- [ ] Sweden

**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.

**Study status**

Finalised

# Research institutions and networks

## Institutions

NA

Multiple centres: 16 centres are involved in the study

# Contact details

**Study institution contact**

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**Study contact**

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**Primary lead investigator**

Tor Melin

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**
Actual: 06/08/2013

**Study start date**
Planned: 13/09/2013

Actual: 19/08/2013

**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

**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

**Name of medicine, 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…

# 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**

No