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

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28191

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

Sylvia Simon

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

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:

Primary data collection

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.

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)

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

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