The value of new and functional iron status indicators to guide iron supplementation in anemia of inflammation

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anaemias nonhaemolytic and marrow depression
Study type	Observational invasive

Summary

ID

NL-OMON36019

Source
ToetsingOnline

Brief title
iron supplementation in chronic inflammation

Condition

- Anaemias nonhaemolytic and marrow depression

Synonym
ferriprive anemia, iron deficiency anemia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: NIH

Intervention

Keyword: anemia, chronic inflammation, iron deficiency, iron supplement

Outcome measures

Primary outcome

The main study parameter is to determine whether the change in Ret- He, RBC- He and hepcidin concentration from baseline to one or two weeks iron supplemental therapy predicts the increase in hemoglobin concentration after 6 weeks of oral iron supplementation therapy;

Secondary outcome

Secondary objectives are to (1) assess the predicting value of Ret- He, RBC- He and hepcidin concentration at baseline (before therapy) to increase the hemoglobin concentration after six weeks of oral iron supplementation therapy; (2) to compare the value of conventional iron status parameters ferritin, transferrin saturation, soluble transferrin receptor and iron with the novel iron parameters to predict the response of one, two and six weeks oral iron supplementation therapy defined by an increase in hemoglobin concentration.

Study description

Background summary

Iron deficiency anemia is difficult to assess during inflammatory conditions, since conventional iron parameters are affected by inflammation. It is currently unknown which patients benefit from iron supplementation therapy. However, new iron parameters that offer a functional measure of iron incorporation have recently become available. These parameters include the iron incorporation into hemoglobin of reticulocytes (Ret- He)and erythrocytes (RBC-

He) and the iron regulatory hormone hepcidin. A change in these functional iron parameters to a short course of iron therapy may enable us to study whether iron is absorbed and incorporated into red blood cells.

Study objective

We aim to determine whether the change in Ret- He, RBC- He and hepcidin concentration to one or two weeks iron supplementation therapy predicts the increase in hemoglobin concentration after 6 weeks of oral iron supplementation therapy in anemic patients with chronic inflammation. Moreover, we aim to assess whether Ret- He, RBC- He and hepcidin concentration at baseline (before therapy) a response in hemoglobin concentration after six weeks of oral iron supplementation therapy. Also, we would like to compare the value of conventional iron status parameters ferritin, transferrin saturation, soluble transferrin receptor and iron with the novel iron parameters in predicting the response of one, two and six weeks oral iron supplementation therapy.

Study design

The study is designed as an explorative intervention study.
Intervention: Patients will receive ferrous fumarate 200 mg bid during six weeks.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Venous blood samples will be drawn at four time points and include one tube of 3 ml and one tube of 8,5 ml. At baseline one sample includes a standard of care complete blood count of which additional parameters will be assessed, the other three assessments require an extra visit, although all efforts will be undertaken to combine this visit with regular standard of care. Ferrous fumarate is a well tolerated drug with longstanding experience in usage to treat iron deficiency. The expected adverse events for this short period of prescription are minor and reversible, and may include mainly nausea, stomach- ache, diarrhoea or constipation. This study protocol requires no additional physical examinations, nor questionnaires or diaries to be filled in.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-above 18 years old
-an active chronic inflammatory or infectious disorder with CRP >10 mg/L (defined by the treating medical specialist)
- anemia (defined as hemoglobin concentration below 7.0 mmol/l and 7.5 mmol/l for women and male, respectively).

Exclusion criteria

-not able to take oral medication
-using iron supplements in the previous month
-using erythropoietin
-requiring blood transfusion
-renal and liverfailure

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	27-09-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL36720.091.11