Prospective Open label study of Parenteral vs Enteral iron in Young IBD patients and Effect on physical fitness

Published: 18-07-2013
Last updated: 19-03-2025

To examine if intravenous administration of iron ismore efficacious than oral iron in improvement offitness scores, iron status and reduction of fatigue

Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON44995

Source
ToetsingOnline

Brief title
POPEYE study

Condition

- Gastrointestinal inflammatory conditions
- Autoimmune disorders

Synonym
Inflammatory Bowel Disease - chronic infection of the intestines

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Vifor Pharma;farmaceutische industrie,Vifor Pharma

Intervention

Keyword: 6 minute walking test, anemia, children and adolescents, intravenous ferric carboxymaltose

Outcome measures

Primary outcome

8.1.1 Main study parameter/outcome

Primary outcome is the proportion of patients per group that show a 15%

increase in 6 minute walking distance from study baseline.

The six minute walktest (6MWT) is an established method to assess exercise

capacity. It is expressed as the distance a person can walk at a constant,

uninterrupted pace in 6 minutes {2002 263 /id}. The patients are asked to walk

up and down the measured lap at their best pace but not to run or race. With

patients tested by the same technician, short-term reproducibility of the 6MWT

is excellent {2002 263 /id}. 6MWT is expressed as absolute distance in meters

and is age and height dependent {Geiger, 2007 557 /id;Lammers, 2008 558 /id}.

Secondary outcome

8.1.2 Secondary outcome variables:

Secondary outcome variable in the study is an increase of Hb with 1.25 mmol/L

(2 g/dl) one month after administration of IV ferric carboxymaltose therapy

compared to the Hb level at time of inclusion

Other secondary endpoints include the IMPACT-III score and the PEDSQL fatigue

scale.

The IMPACT-III score is a disease-specific quality

of life score, composed of 35 items on 6 domains: IBD-related symptoms (7 items), systemic symptoms (3), emotional functioning (7), social functioning (12), body image (3) and treatment/intervention-related concerns (3).[26,27] Each item can be scored on a 5 point Likert scale, coded from 0 to 4 points. Higher scores indicate better quality of life. The IMPACT questionnaire is validated for use in children 8 years and older and is recommended for the evaluation of new therapies because of its high sensitivity to change. The IMPACT-III (NL) is a translated and modified version of the original Canadian questionnaire that used a visual analogue scale.[28,29] The Likert scale was introduced as it has been shown that children consider it easier to complete than a visual analogue scale.

The PEDSQL fatigue scale: The developed 18-item PedsQL Multidimensional Fatigue Scale was designed to measure fatigue in pediatric patients and comprises the General Fatigue Scale (6 items), Sleep/Rest Fatigue Scale (6 items), and Cognitive Fatigue Scale (6 items). (Varni, 2004) The questionnaire is available in Dutch for children (8-12y) and adolescents (12-18y). The questionnaire comprises parallel child self-reports and parent proxy-reports. The participants rate how often a particular problem occurred in the past month, using a 5-point Likert scale. Each item is reverse-scored and rescaled to 0-100

scale, so that higher scores indicate fewer symptoms of fatigue.

Also monitored parameters are the clinical disease activity according to PCDAI

and PUCAI,

laboratory markers for effectiveness of IV iron therapy in replenishment of

iron stores/biomarkers for iron stores (Ht, cell indices, thrombocytes,

ferritin, transferrin, serum iron level, transferrin saturation, reticulocytes

, sTfR, CRP, soluble transferrin receptors to log ferritin (sTfR-F ratio),

transferrin/log ferritin ratio, hepcidin), side effects of IV iron therapy on

liver functioning (AST, ALT, AF, total protein, albumin) and side effects on

electrolyte homeostasis (phosphate).

Study description

Background summary

Inflammatory bowel disease (IBD) in children and adolescents is often associated with anemia. Anemia in IBD has multiple etiologies and there is often a combination of iron
At the time that children are diagnosed with inflammatory bowel disease (IBD) over 80% of them are anemic with iron deficiency being the most common cause. Despite reaching remission, fatigue and decreased physical fitness continue to disturb activities of daily living. For children, this can be the most debilitating aspect of their disease.
In order to replete empty iron stores administration of iron is recommended, yet the preferred route of administration has not been determined in children. Data about efficacy and optimal timing of IV and oral iron administration in pediatric patients are lacking.
We hypothesize that children with IDA receiving IV iron therapy in comparison to oral iron therapy will have faster recovery from anemia in terms of Hb and other hematologic parameters and

perform better in tests for fitness and score lower in fatigue scales.

Study objective

To examine if intravenous administration of iron is more efficacious than oral iron in improvement of fitness scores, iron status and reduction of fatigue

Study design

Prospective, multicentre randomised clinical trial comparing IV and oral iron administration in children and adolescents with IBD

Intervention

Intravenous administration of ferric carboxymaltose (intervention):
The study medication is ferric carboxymaltose or ijzercarboxymaltose in Dutch, brand name Ferinject ® (The Netherlands) or Injectafer® (Belgium) . Intravenous ferric carboxymaltose has several potential benefits in the treatment of anemia in children with IBD over oral therapy or other intravenous formulations. Studies performed in both adult and pediatric populations indicate a faster correction of anemia, a more profound replenishment of iron stores and fewer side effects compared to oral supplementation (8,9,10). The benefit of ferric carboxymaltose over other intravenous formulations is the possibility to safely treat anemia in a single intravenous dose. Especially in children this is more patient-friendly.

Usual care
Standard medical treatment is provided to the patients as an oral iron supplement (ferrofumarate), dosing will be 9 mg/kg/day in 2 doses with a maximum of 600 mg (according to a frequently used dutch formulary, www.kinderformularium.nl).
Medication will be provided as a suspension or as a tablet, depending on the preference of the patient and the possibility to reach the correct dose when using tablets.

Study burden and risks

In the intervention group, risks attributed to the intravenous iron therapy are hypersensitivity reactions, headache and dizziness and with paravenous leakage brown discolouration and irritation of the skin may occur.
The number of venapunctures for sampling is the same for both groups and is not different from routine patient care. However, collection of stool samples and completion of questionnaires needs to be done periodically. The 6 minute walking test will be done at baseline, 4- and 12 weeks later and 6 months after

start of study.

Benefit in the intervention group is that patients will have more information about their disease state, laboratory values and fitness.

Contacts

Public
Atrium Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL
Scientific
Atrium Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

*1. Children attending a pediatrician/ pediatric gastro-enterologist/gastro-enterologist.
2. Children aged 8 * 20 years
3. Suffering from CD/CU/IBDU diagnosed according to the Porto criteria (1)

4. Written informed consent of both parents with authority or from custodial parent and if age> 12y: also from the child itself.
5. Ability to understand and speak Dutch language.

Exclusion criteria

1. Allergic reactions to intravenous iron therapy
2. Suffering from hemochromatosis or other iron overload disease
3. Patients who received oral/ intravenous iron therapy three months prior to the study
4. PUCAI > 65 - PCDAI > 30 (severe disease activity)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-06-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ferinject
Generic name:	ferric carboxymaltose
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	18-07-2013
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	23-12-2014
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	21-02-2017
Application type:	Amendment
Review commission:	METC Atrium-Orbis-Zuyd
Approved WMO Date:	23-02-2017
Application type:	Amendment
Review commission:	METC Atrium-Orbis-Zuyd
Approved WMO Date:	06-02-2018
Application type:	Amendment
Review commission:	METC Atrium-Orbis-Zuyd

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27310
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-005644-26-NL
CCMO	NL42995.096.12
OMON	NL-OMON27310