Studie naar de effectiviteit van ijzer dat via de ader wordt gegevens ten opzichte van ijzer dat via de mond wordt gegeven bij kinderen met een chronische darmziekte.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27310

Source
NTR

Brief title
POPEYE study

Health condition

IBD, pediatric, anemia, 6minute walking test ,physical fitness, parenteral iron, oral iron

Dutch: chronische darmziekte, kinderen, 6 minuten wandel test, fysieke gezondheid, intraveneuze ijzertoediening, orale ijzertoediening

Sponsors and support

Primary sponsor: Atrium Medical Centre, Heerlen, the Netherlands
Source(s) of monetary or material Support: Investigator initated research. Sponsor: Atrium Medical Centre, Heerlen, the Netherlands
Funding: Vifor Pharma

Intervention

Outcome measures

Primary outcome

Primary outcome is the proportion of patients per group that show a 15% increase in 6 minute walking distance from study baseline.

Secondary outcome

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.
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

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

Use of IV iron:
1. improves exercise capacity quicker than oral iron;
2. causes a quicker rise in Hb than oral iron;
3. replenishes body iron stores better than oral iron;
4. reduces fatigue scores quicker than oral iron

Study design

Measurement of biochemistry and 6 MWT and questionnaires at 1, 3, 6 months after start of the study.

Intervention

Intervention is administration of ferric carboxymaltose versus oral iron adminstration for children who are anemic and suffering from IBD.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children attending a pediatrician/ pediatric gastro-enterologist
2. Children aged 8 – 18 years
3. Suffering from CD/CU (diagnosed according to Porto criteria) (1)
4. Written informed consent of both parents with authority or from legal guardian and if age> 12y: also from the child itself
5. Ability to understand and speak Dutch language

6. Hemoglobin level below 2 SD for gender and age (see appendix 2)
7.Ferritin ≤ 50 µg/L

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2014
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44995
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4249
NTR-old	NTR4487
CCMO	NL42995.096.12
OMON	NL-OMON44995

Study results

Summary results
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