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.

Gepubliceerd: 03-04-2014 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27310

Bron
NTR

Verkorte titel
POPEYE study

Aandoening

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

Ondersteuning

Primaire sponsor: Atrium Medical Centre, Heerlen, the Netherlands
Overige ondersteuning: Investigator initated research. Sponsor: Atrium Medical Centre, Heerlen, the Netherlands

Funding: Vifor Pharma

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44995
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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