Iron status in children with inflammatory bowel disease

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Inflammatory bowel disease (IBD) is characterized by chronic inflammation of the intestinal tract with alternating periods of remission and exacerbation. Anemia is the most common extraintestinal complication of IBD. Studies of children with IBD…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26055

Bron
Nationaal Trial Register

Verkorte titel
IRO-IBD

Aandoening

Children, Inflammatory Bowel Disease (IBD), Iron deficiency

Ondersteuning

Primaire sponsor: Juliana Children's Hospital/Haga Hospital
Overige ondersteuning: Juliana Children's Hospital/Haga Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To establish the prevalence of anemia, ID and IDA in children with IBD

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Anemia is highly prevalent in pediatric patients with inflammatory bowel disease (IBD). The most common types of anemia in IBD are iron-deficiency anemia (IDA) and anemia of chronic disease (ACD), and these conditions frequently coexist. Between 40% - 88% of cases of anemia in children with IBD results from iron deficiency (ID). Absolute ID can result from inadequate dietary intake, malabsorption of iron, or chronic intestinal blood loss. In functional ID, as in ACD, iron homeostasis is disturbed which leads to iron-restricted erythropoiesis. Screening for ID(A) in children with IBD is important because ID(A) in childhood is associated with numerous adverse effects. The effect of iron supplementation in IBD patients likely depends upon the underlying cause; patients with an absolute ID might benefit from iron supplementation whereas in functional ID underlying inflammation should be treated before iron is supplemented. Accurate assessment of iron status is therefore highly important in the diagnosis and treatment of ID(A) in IBD patients.

Objective: To assess iron status, prevalence and risk factors of ID(A) in children with IBD. We will also investigate which parameters can differentiate between IDA and ACD.
Study design: A descriptive, observational study
Study population: Approximately 100 children, aged 0-18 years, being treated for IBD in the Juliana Children's Hospital/ Haga Hospital in The Hague, The Netherlands will be included in the study.

Intervention: According to the national and local health care standard, all children with IBD undergo regular check-ups. As part of these regular check-ups blood is taken to evaluate disease activity and check for possible anemia and/or ID. Therefore, no extra blood needs to be taken. Data concerning demographics, dietary intake, anthropometry, medication, disease activity and infections/inflammation, will be gathered from reviewing all the medical records.

Main study parameters/endpoints: Absolute ID will be classified when serum ferritin (SF) is < 12 µg/L in patients < 5 years of age and < 15 µg/L in patients > 5 years of age (WHO 2001) in absence of infection or inflammation (CRP < 10 mg/L). IDA is defined as absolute ID in combination with a low hemoglobin (Hb). Functional iron deficiency (ID) will be classified when zinc protoporphyrin (ZPP) is > 61 mmol/mol haem in patients < 5 years of age and >70 mmol/mol haem in patients > 5 years of age (WHO 2001) and/or red cell distribution width (RDW) is > 14 %. ACD will be defined as functional ID in combination with low Hb-level.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: No extra blood needs to be taken and there will be no extra burden for participating children.

Doel van het onderzoek

Inflammatory bowel disease (IBD) is characterized by chronic inflammation of the intestinal

tract with alternating periods of remission and exacerbation. Anemia is the most common extraintestinal complication of IBD. Studies of children with IBD report prevalences of anemia between 41% and 75%, depending on inclusion criteria, time of measurement and the used definition of anemia. The two most common causes of anemia in IBD patients are iron deficiency anemia (IDA) and anemia of chronic disease (ACD), and these conditions frequently coexist. Absolute iron deficiency (ID) is caused by a reduced iron intake, either from dietary deficiency or malabsorption, or increased losses. Chronic blood loss from the gastrointestinal tract, due to chronic inflammation of the intestinal epithelium, is the most common mechanism of ID. IDA occurs when iron stores are exhausted and the supply of iron to the bone marrow is compromised. In functional ID inflammatory mediators, present in patients with active IBD, induce changes in iron homeostasis, with increased uptake and retention of iron within cells of the reticuloendothelial system. This leads to a diversion of iron from the circulation in to storage sites of the reticuloendothelial system, subsequent limitation of the availability of iron for erythroid progenitor cells, and iron-restricted erythropoiesis. This will ultimately lead to the so-called anemia of chronic disease (ACD).
ID(A) in childhood is associated with numerous adverse effects, such as an increased risk of impaired neurodevelopment, growth retardation and impaired immune response. Therefore, screening for and treatment of ID(A) in children with IBD is important. The effect of iron supplementation in IBD patients likely depends upon the underlying cause; patients with an absolute ID might benefit from iron supplementation whereas in functional ID as in ACD underlying inflammation should be treated before iron is supplemented. Accurate assessment of iron status and differentiation of IDA and ACD is therefore highly important in de diagnosis and treatment of ID/anemia in IBD patients (Pels 2010, Wilson 2004).
In this study we will assess the prevalence and risk factors for anemia and ID(A) in children with IBD. We will also investigate whether we can differentiate between IDA and ACD by measuring several biomarkers reflecting different aspects of iron homeostasis.

Onderzoeksopzet

One regular check-up moment at the ambulant clinic

Onderzoeksproduct en/of interventie

No intervention.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Children (male and female), up to 18 years of age

- Diagnosis of IBD based on conventional endoscopic, histological and radiological criteria in accordance with the Porto-criteria

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- oncologic disorder

- known hemoglobinopathies

- congenital malformations

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-11-2014
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-11-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4780
NTR-old	NTR4919
Ander register	: 14-092 METC

Resultaten