Iron status in children with cystic fibrosis.

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

Samenvatting

ID

NL-OMON27557

Bron
Nationaal Trial Register

Verkorte titel
IROCYF

Aandoening

cystic fibrosis
iron status
sputum iron

Ondersteuning

Primaire sponsor: Peformers: Juliana Children's Hospital
Overige ondersteuning: Juliana Children's Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Serum and sputum iron content.

Toelichting onderzoek

Achtergrond van het onderzoek

Iron deficiency (ID) is common in children and adolescents with cystic fibrosis (CF). Proposed mechanisms for ID in CF may involve absolute ID and/or ID due to chronic inflammation. There are no data on the causes ID in children with CF.
Sputum from adult patients with CF contains increased amounts of total iron and ferritin and decreased amounts of transferrin compared with healthy controls. A significant relationship between the iron content of the CF lung microenvironment and the quantitative load of Pseudomonas Aeruginosa (PA) was demonstrated.

The study proposed here will investigate the prevalence and etiology of ID in children with CF. Furthermore we will investigate the sputum iron content in children with CF and the relationship with PA.

Doel van het onderzoek

Our hypothesis is that ID in children with CF is common, and is caused by the combination of an absolute- and a functional-ID, which leads to relative anemia. In this study we will investigate the prevalence and etiology of ID in CF children.
Furthermore we expect to find increased sputum iron concentrations in children with CF compared with controls, due to increased hepcidin production.

Onderzoeksopzet

We estimate iron content in serum and sputum during standard annual check-up.

Onderzoeksproduct en/of interventie

According to our actual standard protocol, all children with CF undergo an annual check-up in the Juliana children’s hospital. During this check-up we perform a pulmonary function test in children >6 years and obtain sputum, blood and defecation samples to analyze pulmonary and gastrointestinal status. Parents/caretakers are asked to keep up a food diary for their child for a period of 3 days.
In addition to blood sampling as part of the regular check-up, extra blood will be taken to evaluate iron status. In sputum samples obtained during pulmonary function test we will assess iron, ferritin and total cell counts.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male and female children, aged 0-18 years;

2. Diagnosed with CF based on accepted clinical criteria; typical clinical history, altered pulmonary function, elevated levels of sodium and chloride in repeated sweat test;

3. Written informed consent from parents/guardian and children themselves if >12 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Children with a history of haemoptysis within the preceding month are excluded from sputum analysis.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-01-2012
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	NL3083
NTR-old	NTR3231
Ander register	: 11-097
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A