Iron status in children with cystic fibrosis.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27557

Source
Nationaal Trial Register

Brief title
IROCYF

Health condition

cystic fibrosis
iron status
sputum iron

Sponsors and support

Primary sponsor: Peformers: Juliana Children's Hospital
Source(s) of monetary or material Support: Juliana Children's Hospital

Intervention

Outcome measures

Primary outcome

Serum and sputum iron content.

Secondary outcome

1. Demographics;

2. Pulmonary function test;

3. Dietary information;

4. Clinical severity of disease;

5. Infections;

6. Medication;

7. Anthropometry.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

Public
Juliana Kinderziekenhuis
Sportlaan 600
Lieke Uijterschout
Den Haag 2566 MJ
The Netherlands
+31 (0)70 2100000
Scientific
Juliana Kinderziekenhuis
Sportlaan 600
Lieke Uijterschout
Den Haag 2566 MJ
The Netherlands
+31 (0)70 2100000

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

analysis.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2012
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	12-01-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3083
NTR-old	NTR3231
Other	: 11-097
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A