Sinonasal pathology in children with Cystic Fibrosis

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Investigation of the prevalence of sinonasal disease on CT-sinus in children with Cystic Fibrosis at different ages. This study will focus especially on the onset of sinonasal pathology in Cystic Fibrosis in relation to the development of the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON38689

Source
ToetsingOnline

Brief title
SINAS study

Condition

- Respiratory disorders congenital
- Bacterial infectious disorders
- Upper respiratory tract disorders (excl infections)

Synonym
Cystic Fibrosis, mucoviscidosis, rhinosinusitis

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Longfonds;afdeling longziekten HagaZiekenhuis

Intervention

Keyword: Children, Cystic Fibrosis, Sinonasal pathology

Outcome measures

Primary outcome

Lund-Mackay scores on CT-sinus in children with CF.

Secondary outcome

Secondary study parameters will be the outcome of nasal cultures, symptoms of

sinonasal disease and anatomic variations in the sinonasal area.

Study description

Background summary

Sinonasal pathology in Cystic Fibrosis is very common. This genetic disease predisposes a patient to the development of i.e. rhinosinusitis and/or nasal polyps. Previous research in patients with CF showed a prevalence of 74-100% of rhinosinusitis and 32-57% of nasal polyps. Moreover a very high prevalence of anatomical abnormalities on computed tomography of the paranasal sinuses was seen. Smaller paranasal sinuses, abnormal anatomy of the ostiomeatal complex and bony changes of the sinus walls have been described. These findings indicate a chronic course of sinonasal pathology. However, to date the onset and the pathogenesis of this sinonasal pathology in Cystic Fibrosis is unclear. More knowledge on the pathogenesis of sinonasal disease in CF is necessary to develop an accurate treatment protocol for this pathology in CF. This research also might result in early interventions on sinonasal pathology. Early interventions may prevent a chronic course of sinonasal pathology and eventually less complaints in adult life.

Study objective

Investigation of the prevalence of sinonasal disease on CT-sinus in children with Cystic Fibrosis at different ages. This study will focus especially on the onset of sinonasal pathology in Cystic Fibrosis in relation to the development of the sinuses and bacterial infections.

Study design

Cross-sectional study.

Study burden and risks

In this study the patient will visit the hospital once. During this visit computed tomography of the paranasal sinuses and a nasopharyngeal swab are performed. In the Haga Teaching Hospital a dual source flash CT-scan will be used to minimize the radiation dose. The estimated total dose of this CT-scan is approximately 1 mSv. In the AMC a Philips Brilliance CT is used with an estimated effective dose of 1 mSv. Since sinonasal disease in Cystic Fibrosis is common, but the pathogenesis and the onset remain unclear, it is important to study CT-sinuses in this particular group. This study can contribute to development of an evidence based treatment and monitoring protocol for sinonasal pathology in CF.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

* Confirmed diagnose of Cystic Fibrosis based on genotyping or a positive sweat test
* Age * 0 and <18 years

Exclusion criteria

* Gross immunodeficiency (congenital of acquired)
* Congenital mucociliary problems other than CF (e.g. Primairy ciliary dyskinesia)
* ASA syndrome (Samter*s triad; nasal polyps, asthma, and aspirin sensitivity)
* Intranasal neoplasia
* Systemic vasculitis and granulomatous diseases (e.g. M. Wegener, sarcoidosis, Churg-Strauss syndrome)
* Recently (within 1 month) CT-sinus performed

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	23-07-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23697
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL43794.098.13
OMON	NL-OMON23697