

Neus(bijholten)problemen bij kinderen met Cystic Fibrosis.

No registrations found.

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

Summary

ID

NL-OMON23697

Source

Nationaal Trial Register

Brief title

SINAS study

Health condition

Cystic Fibrosis (CF)

Sponsors and support

Primary sponsor: Haga Teaching Hospital

Source(s) of monetary or material Support: Lungfund Haga Teaching Hospital

Intervention

Outcome measures

Primary outcome

Opacification of sinuses on CT-scan (Lund-Mackay score)

Secondary outcome

- Development of paranasal sinuses

- Severity of CF
- Onset of sinonasal pathology
- Symptoms of sinonasal disease
- Outcome of nasopharyngeal swab
- Anatomic variations in sinonasal area
- Outcome of lower airway culture

Study description

Background summary

Adult CF patients often display signs of chronic rhinosinusitis on a CT-scan. However, to date the onset and the pathogenesis of this sinonasal pathology in Cystic Fibrosis is unclear. By studying children with CF from birth until 18 years, more knowledge on the onset of sinonasal disease can be gathered. More knowledge on the pathogenesis of sinonasal disease is necessary to develop an accurate treatment protocol for this pathology. Early interventions may prevent a chronic course of sinonasal pathology and eventually less complaints in adult life.

Study objective

N/A

Study design

Study procedures performed in one day

Intervention

Observational study:

- CT-sinus
- Nasopharyngeal swab
- Lower airway culture

Contacts

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Eligibility criteria

Inclusion criteria

- Confirmed diagnosis of Cystic Fibrosis based on genotyping or a positive sweat test
- Age 0-<18 years

Exclusion criteria

- Gross immunodeficiency (congenital or acquired)
- Congenital mucociliary problems other than CF (e.g. Primary Ciliary Diskinesia)
- ASA syndrome (Samter's trias; 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 non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2013
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion	
Date:	05-09-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38689
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3989
NTR-old	NTR4161
CCMO	NL43794.098.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38689

Study results

Summary results

N/A