Neusbijholteontstekingen en neuspoliepen bij volwassenen met taaislijmziekte.

No registrations found.

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

Summary

ID

NL-OMON28476

Source
Nationaal Trial Register

Brief title
Sinonasal pathology and CF

Health condition

Cystic Fibrosis, nasal polyps, rhinosinusitis,
Taaislijmziekte, neuspoliepen, rhinosinusitis

Sponsors and support

Primary sponsor: H.G.M. Heijerman, MD PhD & M.C. Berkhout, MD
Pulmonary Department
Haga Teaching Hospital, The Hague
Source(s) of monetary or material Support: Study related intervention are covered by standard care.
Personel costs are met from a private researchfund.

Intervention

Outcome measures

Primary outcome

Prevalence of rhinosinusitis and/or nasal polyps.

Secondary outcome

1. Disease specific quality of life (score on Rhinosinusitis Outcome Measure-31);

2. Outcome of ENT examination (on a standardized form);

3. Upper airway cultures (nasal lavage and middle meatal swabs);

4. Sputum cultures;

5. Nasal airway resistance;

6. Computed tomography of sinuses and volume estimation of sinuses.

Study description

Background summary

N/A

Study objective

Prevalence of rhinosinusitis and nasal polyps in CF patients is higher.

Study design

One visit for each subject.

Prevalence of rhinosinusitis and/or nasal polyps can be estimated after 100 patients, approximately after one year.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Confirmed diagnose of Cystic Fibrosis based on genotyping or a positive sweat test;

2. Age equal to or above 18 years.

Exclusion criteria

1. Gross immunodeficiency (congenital of acquired);

2. Congenital mucociliary problems other than CF (e.g. Primairy ciliary dyskinesia);

3. ASA syndrome (Samter's triad; nasal polyps, asthma and aspirin sensitivity);

4. Cocaine abuse;

5. Intranasal neoplasia;

6. Systemic vasculitis and granulomatous diseases (e.g. M.Wegener, sarcoidosis, Churg-Strauss syndrome);

7. Allergy or intolerance to xylometazoline and lidocaine;

8. Pregnancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-04-2011
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-09-2011
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	NL2941
NTR-old	NTR3088
Other	METC : 11-010
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A