# Rhinosinusitis and nasal polyps in adults with Cystic Fibrosis

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Investigate the prevalence of rhinosinusitis and/or nasal polyps in adult patients with Cystic Fibrosis. Also several aspects of sinonasal disease are investigated; quality of life, correlation between phenotype and genotype, microbiology, anatomy...

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

## Summary

### ID

NL-OMON36309

**Source**
ToetsingOnline

**Brief title**
Sinonasal pathology and CF

### Condition

- Respiratory disorders congenital
- Hepatobiliary neoplasms malignant and unspecified
- Upper respiratory tract disorders (excl infections)

**Synonym**
Cystic Fibrosis: mucoviscidosis, rhinosinusitis: paranasal sinus infection, sinusitis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** HagaZiekenhuis
**Source(s) of monetary or material Support:** eigen middelen

## Intervention

**Keyword:** Cystic Fibrosis, Polyposis Nasi, Rhinosinusitis

## Outcome measures

### Primary outcome

Prevalence of rhinosinusitis and/or nasal polyps.

### Secondary outcome

Disease specific quality of life, outcome of ENT examination, nasal cultures,

sputum culture, computed tomography of sinuses and nasal airway resistance.

# Study description

### Background summary

The pathophysiology of Cystic Fibrosis predisposes patients to the development of sinonasal disease, i.e. rhinosinusitis and polyposis nasi. Dysfunction of the chloride transport channel also results in viscous mucus in the upper airways, which leads to bacterial overgrowth and infection. However, little is known about the actual prevalence and the influence of sinonasal pathology on the general health of a CF patient.
Nowadays CF patients have an increased life expectancy because of better therapeutic modalities and centralised care. As a consequence therapy focuses increasingly on improvement of quality of life. Sinonasal pathology has a great negative influence on general quality of life. Previous research shows that these symptoms have a greater negative influence compared to symptoms of congestive heart failure, COPD and back pain.
Moreover previous studies hypothesize that the upper airways can be a reservoir for bacteria which leads to cross-infection between the upper airways and the lower airways. Thus, in theory pneumonias can be prevented by adequately treating the upper airway infection.
Research in the prevalence of rhinosinusitis and nasal polyps in patients with CF is scarce. Besides sinonasal disease in patients with Cystic Fibrosis are currently underdiagnosed and therefore undertreated. This shows that it is important to do solid research in the prevalence of this condition.
More knowledge of the actual prevalence, the impact of the symptoms on quality of life and the severity of these symptoms, is essential to make a first step in accurate treatment and a national protocol regarding sinonasal disease in CF. In conclusion this can lead to improvement of the general health of the CF

patient.

### Study objective

Investigate the prevalence of rhinosinusitis and/or nasal polyps in adult patients with Cystic Fibrosis. Also several aspects of sinonasal disease are investigated; quality of life, correlation between phenotype and genotype, microbiology, anatomy of the paranasal sinuses and nasal airway resistance.

### Study design

Cross-sectional multicenter study.

### Study burden and risks

In this study the patient will visit the hospital once, preferably subsequently to a regular visit. The total time of this visit is estimated two hours. At this visit the subjects will fill in a questionnaire. Also they will undergo physical examination determined by ENT examination, nasendoscopy, nasal lavage, middle meatal cultures, sputum culture, measurement of NAR and CT scan of the sinuses. Radiation risk of the CT sinus is considered to be small compared to the annual background radiation. The relative risk of radiation-induced cancer is small. Possible discomfort of the nasendoscopy and the middle meatal culture, will be prevented by the administration of local anaesthesia. Theoretically it could be possible that nasal bacteria are spread as a consequence of the nasal lavage. Although this has never been reported in practice. This spread of bacteria could cause pulmonary infections. The researchers will carefully record complications that occur after the nasal lavage.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1. Confirmed diagnose of Cystic Fibrosis
2. Age * 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. Pregnancy

# Study design

## Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-04-2011 |
| Enrollment: | 100 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 22-03-2011 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>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

No registrations found.

### In other registers

| Register | ID |
|---|---|
| CCMO | NL35139.098.11 |