# Early detection of bacterial airway infections in children with primary ciliary dyskinesia and cystic fibrosis by electronic nose

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We hypothesize that expiratory VOC-analysis by electronic nose is capable of: a.) discriminating CF-/PCD-patients with and without pulmonary infections and b.) discriminating CF-/PCD-patients and healthy controls.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Respiratory disorders congenital |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON33077

**Source**
ToetsingOnline

**Brief title**
Detection of airway infections in CF and PCD with the electronic nose

### Condition

- Respiratory disorders congenital
- Respiratory tract infections

**Synonym**
Cystic Fibrosis, immotile cilia syndrome, mucoviscoidosis / Primary ciliary dyskinesia

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Airway infections, CF, Electronic nose, PCD

## Outcome measures

### Primary outcome

The primary outome of this study will be:

- the discrimination between CF and PCD patients with and without pulmonary

infections

- the discrimination between CF, PCD and healthy controls

### Secondary outcome

none

# Study description

### Background summary

Early diagnosis of cystic fibrosis (CF) and primary ciliary dyskinesia (PCD) combined with swift identification and treatment of pulmonary infections is important for the preservation of pulmonary function, quality of life and life expectancy. At present, the gold standard for determining pathogens in airways of CF- and PCD-patients is culturing of sputum specimens. However, sputum production is often minimal or absent in children and thus alternative methods such as cough swabs and sometimes even bronchoalveolar lavage or serological tests are used. These methods require specialized expertise, are time-consuming and expensive, and can be rather invasive. A possible novel method that is non-invasive and not dependent on sputum expectoration is the analysis of exhaled breath by electronic nose. Preliminary data obtained by our group indicates that in vitro classification of CF-derived P. aeruginosa and S. aureus is feasible using the electronic nose.
In addition, it may be possible to identify specific smell-prints of CF- and PCD-patients. One of the features of exhaled breath in PCD-patients, a low

nasal NO, is already being used in clinical practice to support or reject this diagnosis. The analysis of thousands of volatile organic compounds (VOC) by electronic nose may even have more potential and can possibly, if specific VOC-profiles are identified, make a contribution to the initial diagnostic work-up of children suspected of CF or PCD.

### Study objective

We hypothesize that expiratory VOC-analysis by electronic nose is capable of: a.) discriminating CF-/PCD-patients with and without pulmonary infections and b.) discriminating CF-/PCD-patients and healthy controls.

### Study design

The study has a case-control, cross sectional design comparing CF and PCD patients with healthy controls en CF and PCD patients with and without pulmonary infections.
Cough swabs and sputum cultures will be taken as part of routine follow-up of CF- and PCD patients at 3 monthly intervals. After informed consent has been obtained, a breath samples will be taken and analyzed by means of discriminant analysis on principal component reduction.

### Study burden and risks

The collection of expiratory air is totally non-invasiveand thus without any health risk.

## 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

Patients: children 0 - 17 years old with cystic fibrosis or primary ciliary dykinesia
Healthy controls: children 0 - 17 years old without pulmonary, metabolic, or inflammatory diseases

## Exclusion criteria

Patients: metabolic, or inflammatory disorders
Healthy controls: pulmonary, metabolic or inflammatory disease

# Study design

## Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 20-03-2009 |
| Enrollment: | 170 |
| Type: | Anticipated |

## Ethics review

Approved WMO

| | |
|---|---|
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 | NL27301.018.09 |