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

No registrations found.

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

Summary

ID

NL-OMON26592

Source
NTR

Brief title
Early detection of airway infections in CF and PCD with the electronic nose.

Health condition

Primary ciliary dyskinesia
Cystic fibrosis

Sponsors and support

Primary sponsor: Academic Medical Center and VU University Medical Center, Amsterdam.

Source(s) of monetary or material Support: Initiator: Academic Medical Center and VU University Medical Center, Amsterdam.

Intervention

Outcome measures

Primary outcome

1. Discrimination of CF-/PCD-patients with and without pulmonary infections;

2. Discrimination of CF-/PCD-patients from healthy controls.

Secondary outcome

Discrimination of different classes (aerobic, anaerobic, gram positive, gram negative strains), or types of bacteria responsible for the infection in vivo.

Study description

Background summary

Background:

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.

Hypothesis:

We hypothesize that expiratory VOC-analysis by electronic nose is capable of:

1. Discriminating CF-/PCD-patients with and without pulmonary infections and;

2. Discriminating CF-/PCD-patients and healthy controls.

Study design:

The CF- and PCD-patients treated in the AMC and VUMC; 99 children with CF (48 AMC, 51 VUMC) and 52 with PCD (6 AMC, 46 VUMC), will be asked to participate in this study. In addition 50 age-matched healthy controls will be included. 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, breath samples will be taken and analyzed by electronic nose. Through pattern recognition algorithms, we will attempt to classify the collected smell prints.

Study objective

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. A possible novel method that is non-invasive and not dependent on sputum expectoration is the analysis of exhaled breath by electronic nose. This could help detect airway infections in an early stage and it might be possible to identify specific smell-prints of CF- and PCD-patients.

We hypothesize that expiratory VOC-analysis by electronic nose is capable of:

1. Discriminating CF-/PCD-patients with and without pulmonary infections;

2. Discriminating different classes (aerobic, anaerobic, gram positive, gram negative strains), or types of bacteria responsible for the infection in vivo;

3. Discriminating CF-/PCD-patients from healthy controls.

Study design

Patients between 0 and 17 years of age attending the department of pediatrics of the Amsterdam Medical Center or the VU Medical Center with CF or PCD will be recruited by their treating physician. Those subjects willing to participate will be asked to perform the eNose measurement. Cough swabs and sputum cultures are already being taken as part of routine follow-up of CF- and PCD patients at regular intervals.

Intervention

No intervention, cross sectional study.

Contacts

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Eligibility criteria

Inclusion criteria

Patients:

Children 0-17 years with cystic fibrosis or primary ciliary dyskinesia.

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:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2011
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-04-2011
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	NL2709
NTR-old	NTR2847
Other	MEC AMC : 09/051
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A