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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26592

Bron
NTR

Verkorte titel
Early detection of airway infections in CF and PCD with the electronic nose.

Aandoening

Primary ciliary dyskinesia
Cystic fibrosis

Ondersteuning

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

Overige ondersteuning: Initiator: Academic Medical Center and VU University Medical Center, Amsterdam.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Discrimination of CF-/PCD-patients with and without pulmonary infections;
2. Discrimination of CF-/PCD-patients from healthy controls.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

No intervention, cross sectional study.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

Patients:

Metabolic or inflammatory disorders.

Healthy controls:

Pulmonary, metabolic or inflammatory disease.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2011
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-04-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2709
NTR-old	NTR2847
Ander register	MEC AMC : 09/051
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A