

Using electronic nose measurements to capture subgroups of children with asthma.

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The analysis of exhaled breath by electronic nose measurements can discriminate between subgroups of children with different levels of asthma control.

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

Samenvatting

ID

NL-OMON25508

Bron

Nationaal Trial Register

Aandoening

asthma control in children

Ondersteuning

Primaire sponsor: Academic Medical Centre
University of Amsterdam

Overige ondersteuning: investigator initiated study

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Asthma control score;

2. VOC's of breath prints in exhaled air by gas chromatography mass spectrometry (GC-MS) and electronic nose (eNose).

Toelichting onderzoek

Achtergrond van het onderzoek

Recent clinical guidelines indicate that asthma management should focus on achieving a good level of asthma control. There seems to be subgroups of patients with remarkable inconsistencies between reported symptoms and the presence of airway inflammation. Therefore, phenotypic evaluation of these patients including reported symptoms and objective parameters of airway inflammation should be considered as the strategy of asthma management. The aim of our study is to explore the possibility of using exhaled breath to discriminate between groups of children with different levels of asthma control.

In this cross-sectional study data will be collected once per patient. Asthma control will be evaluated by questionnaire (in the asthmatic patients). Afterwards exhaled breath, FeNO and spirometry measurements will be performed. Spirometry will be measured at last by hand-held spirometer.

Doel van het onderzoek

The analysis of exhaled breath by electronic nose measurements can discriminate between subgroups of children with different levels of asthma control.

Onderzoeksopzet

This is a cross-sectional study, only one timepoint.

Onderzoeksproduct en/of interventie

This will be a cross-sectional study. Data will be collected once per patient in a period of 6 months, in the same occasion as their routine visit in the outpatient clinics. Asthma control will be evaluated by (C)ACT questionnaire (in the asthmatic patients). Afterwards exhaled breath, fractional exhaled Nitric Oxide (FeNO) and spirometry measurements will be performed. Spirometry will be measured at last by hand-held spirometer.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Males and females aged 6 to 17 years (inclusive);
2. Parent/ guardian must be able to give written informed consent prior to participation in the study, which includes ability to comply with the requirements and restrictions listed in the consent form. Informed consent must be obtained prior to undertaking any study procedures;
3. Assent should be obtained from all children in the study where appropriate;
4. For children in the asthma groups, the diagnosis of asthma should be given by specialists according to the GINA guidelines;
5. For the control-group children should have no known respiratory or other systemic diseases.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known underlying respiratory tract disease like congenital airway abnormalities, cystic fibrosis, primary ciliary dyskinesia, bronchopulmonary dysplasia or bronchiectasis;

2. Known systemic or inflammatory diseases;
3. History or current evidence of an upper or lower respiratory infection or symptoms (including common cold) within 2 weeks of baseline assessment (assessment should be deferred);
4. The child has had a exacerbation (requiring ER attendance or hospital admission and /or a course of high dose OCS for at least 3 days duration) within 4 weeks of the baseline assessment (assessment should be deferred).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	02-05-2012
Aantal proefpersonen:	75
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	25-04-2012
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	NL3257
NTR-old	NTR3410
Ander register	METC AMC : 2012_019
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A