Fingerprints for inflammatory subtypes in asthma

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We postulate that exhaled molecular profiling obtained from *breathprints* by electronic nose:1. Will discriminate eosinophilic asthma from non-eosinophilic asthma2. Is associated with individual biomarkers and specific proteomic profiles in induced...

Ethical review	Approved WMO
Status	Pending
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational invasive

Summary

ID

NL-OMON34697

Source
ToetsingOnline

Brief title
Inflammatory subtypes in asthma

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
asthma, chronic inflammation of the airways

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: GlaxoSmithKline

Intervention

Keyword: asthma, biomarker, eosinophil, subtype

Outcome measures

Primary outcome

eNose breathprints of eosinophilic and non-eosinophilic asthmatic subjects.

Secondary outcome

* Specific molecular components that are associated with eosinophilic and non-eosinophilic asthma as determined by gas-chromatography and mass-spectrometry

* Individual biomarkers and proteomic profiles in sputum, blood, urine, nasal lavage and nasal biopsies predictive for eosinophilic and non-eosinophilic asthma

Study description

Background summary

Based on the presence of eosinophilia in sputum, asthma can be divided into eosinophilic and non-eosinophilic types. There is recent evidence from clinical follow-up studies that inflammatory (sub)phenotyping of patients can help to optimize therapy and disease outcome. Sputum induction by hypertonic saline is generally considered a reliable non-invasive method to assess and monitor airways inflammation. However, the application of sputum analysis is somewhat limited by the requirement of lab facilities and the not-directly available results, so adequate surrogate markers of airway inflammation in asthma are required. Electronic nose (eNose) technology combines the non-invasiveness of measuring exhaled breath with real-time analysis of the complete spectrum of volatiles. We recently showed that the electronic nose is able to discriminate exhaled breath from well-characterized subjects with asthma, COPD and controls. This indicates that an electronic nose offers the opportunity to simplify and improve the monitoring of patients with asthma.

Study objective

We postulate that exhaled molecular profiling obtained from *breathprints* by electronic nose:
1. Will discriminate eosinophilic asthma from non-eosinophilic asthma
2. Is associated with individual biomarkers and specific proteomic profiles in induced sputum, blood, urine, nasal lavage and nasal biopsy specimen

Study design

Cross-sectional study with two visits. Visit 1: screening of clinical characteristics. Visit 2: Collecting measurements by sputum induction, collecting exhaled air, blood withdrawal, nasal lavage and up to 4 nasal biopsies, and collecting urine.

Study burden and risks

For this study there are no major risks involved and the eventual occurrence of a discomfort for the patient will be minimized by the involvement of qualified professionals in the procedures. The only invasive methods in this study include blood withdrawal and 4 nasal biopsies. The patients themselves will not benefit directly from this investigation. However, the group of asthmatic patients may benefit from this study in the future. Gaining further knowledge on the subphenotypes of asthma will aid future discovery of novel diagnostic procedures (like eNose and GC-MS) and therapeutic targets. As such, we consider the balance between risks and discomfort for the patients (low) and the possible benefit for these patient groups in the future (potentially high) acceptable.

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

* Age >18 years
* Clinical presentation of asthma
* Airway hyperresponsiveness, indicated by a positive methacholine challenge with PC20 * 8 mg/ml OR
* reversibility in FEV1 of * 12% predicted
* Requiring inhaled corticosteroids at high doses (* 500 ug ICS fluticasone or equivalent)
* Non-smoking or stopped smoking more than 12 months ago and 10 pack years or less
* No condition or treatment which may increase the risk of bleeding
* No other clinically significant abnormality on history and clinical examination
* Able to give written and dated informed consent prior to any study-specific procedures
- sputum eosinophils > 3% * eosinophilic asthma
- sputum eosinophils < 1% * non-eosinophilic asthma

Exclusion criteria

* Change in the dose of ICS in 4 weeks prior to screening
* A course of oral corticosteroids, antibiotics or a respiratory infection within 4 weeks prior to the study
* Use of anti-leukotrienes, chromoglycates, anti-cholinergics within 4 weeks prior to the study
* Pregnancy
* Concomitant disease or condition which could interfere with the conduct of the study, or which treatment might interfere with the conduct of the study, or which would, in the opinion of the investigator, pose an unacceptable risk to the patient in this study
* Unwillingness or inability to comply with the study protocol for any other reason

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	40
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	NL30897.018.09