Orbitrap mass spectrometry analysis of exhaled breath condensate (EBC) of asthmatic children - a pilot study

Published: 23-07-2007
Last updated: 10-05-2024

The study will be divided into two projects: Reproducibility study: To assess reproducibility of analysis of EBC by means of Orbitrap MS, in asthmatic children, with and without atopy.Correlation study: To correlate the results of Orbitrap MS...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON31658

Source
ToetsingOnline

Brief title
Orbitrap MS analysis of EBC of asthmatic children

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma, recurrent wheezing

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Asthmatic, Children, Exhaled breath condensate, Orbitrap mass spectrometry

Outcome measures

Primary outcome

Reproducibility study: In this study first the reproducibility of EBC profiles

will be assessed. Second, we expect to find different patterns in asthmatic and

healthy subjects and in atopic versus nonatopic subjects.

Correlation study: Correlation between EBC and BALF is the primary study

parameter.

Secondary outcome

n.v.t.

Study description

Background summary

Diagnosing asthma is not simple. Symptoms are non-specific, making it difficult to distinguish asthma from other respiratory diseases. Diagnosing asthma in preschool children is even more difficult because lung function tests can not be performed.
Therefore there is a need for a noninvasive, validated method to phenotype the airway pathology in early childhood wheezing, to rationalize and to improve treatment and avoid unnecessary treatment.
A new method for diagnosing airway disease is collection and analysis of exhaled breath condensate (EBC). EBC analysis provides a non-invasive insight in biochemical and inflammatory activity in pulmonary diseases.
With a new analysing method, Orbitrap MS, a new proteomics technology with very high resolution to derive information on biomolecules, we expect to detect the low concentrations of biomarkers in EBC more easily.

Study objective

The study will be divided into two projects:

Reproducibility study: To assess reproducibility of analysis of EBC by means of Orbitrap MS, in asthmatic children, with and without atopy.

Correlation study: To correlate the results of Orbitrap MS analysis of EBC with bronchoalveolar lavage fluid (BALF) in children.

Study design

This project is a pilot study on reproducibility of EBC analysis and correlation between EBC and BALF by Orbitrap MS. It is a prospective cross-sectional study on asthmatic and healthy children, non-interventional and non-therapeutical.

Study burden and risks

Reproducibility study: Patients and parents will be asked to visit the outpatient clinic for three times. During the first visit EBC will be collected two times; FENO-measurement and a flow volume curve will be done. During the second and third visit, EBC will be collected only once. Patients will be asked to keep a diary for a week during the study. No risks are associated with participation.

Correlation study: Bronchoscopy and bronchoalveolar lavage are performed in subjects who have an indication for bronchoscopy for clinical reasons as indicated by the pediatric pulmonologist. The extra burden is that children will have to perform EBC collection once during a routine outpatient clinic visit.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
3015 GJ Rotterdam
Nederland

Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
3015 GJ Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Reproducibility study:
- Patients between 4 and 18 years
- Able to perform EBC collection/ FENO analysis
- Atopic patients: RAST class 2 or higher for at least one aeroallergen ever
- Healthy controls between 4-18 years with a negative ISAAC questionnaire for asthma, eczema and rhinitis, and normal FENO and flow-volume curve.
- Written informed consent;Correlation study:
- Patients under the age of 18
- Indication for bronchoscopy for clinical reasons as indicated by the pediatric pulmonologist
- Written informed consent

Exclusion criteria

Reproducibility and correlation study:
- Extrapulmonary diseases
- Mental retardation
- Active smoking

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2008
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	23-07-2007
Application type:	First submission
Approved WMO Date:	23-06-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL17198.078.07