Confirmed wheezing in infancy as basis for molecular fingerprinting in the prediction of asthma.

Published: 15-09-2009
Last updated: 05-05-2024

The objective of this study is to test our hypothesis:Hypothesis - We postulate that the development of asthma in preschool children can be captured during the first 2 years of life by a minimally invasive *fingerprint* based on the combination of:...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON33199

Source
ToetsingOnline

Brief title
Dutch Europrevall Asthma study: EuroPA-study

Condition

- Allergic conditions
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
asthma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Nederlands Astma Fonds

Intervention

Keyword: Asthma, Biomarkers, Early prediction, Moleculair fingerprint

Outcome measures

Primary outcome

Primary outcome - Asthma at the age of 5 years, objectively established on basis of a validated combination of symptoms and/or the use of asthma medication, in combination with spirometry and increased bronchial hyper responsiveness, based upon the then applicable international standards.

Secondary outcome

not applicable

Study description

Background summary

Rationale - Young children with confirmed wheeze do already exhibit the major histological features of asthma. There is increasing evidence that microbial and biological characteristics can improve the phenotyping of infants at risk of asthma. The aim of the present study is to use confirmed wheezing as the basis for the application of modern molecular profiling in the prediction of asthma in young children.

Study objective

The objective of this study is to test our hypothesis:

Hypothesis - We postulate that the development of asthma in preschool children can be captured during the first 2 years of life by a minimally invasive *fingerprint* based on the combination of:
a) Confirmed wheezing by doctors confirmation and/or electronic trachea sound recordings.
b) Molecular microbial assessment by (multiplex) PCR analysis in nasopharyngeal aspirates and throat swabs.
c) Molecular pattern recognition by electronic nose of exhaled volatile organic compounds.

d) Molecular profiling in peripheral blood by RNA-expression analysis, cytokine measurements and multiplex antibody assays

Study design

Study design - 3-phase 6 years prospective follow-up study:
* Phase 1 (2 yrs duration): inclusion and baseline assessments in wheezy infants and their healthy age-matched controls during the first 2 years of life.
* Phase 2 (2 yrs duration): monitoring of respiratory symptoms by Asthma Control Questionnaire.
* Phase 3 (2 yrs duration): outcome assessment of the children for the presence of objective criteria for asthma at age 5.

Study burden and risks

- Blood sample: We use Emla creme to sedate the skin and reduce potential infant discomfort. Nevertheless the drawing of blood can hurt and may cause a small bruise. We draw a small volume of blood (5 ml) thus not overstressing the child. Current guidelines (ERS and NHG) advise to draw a venous blood sample for airborne-allergent specifig IgE when a child presents with respiratory wheeze and a suspicion of allergy. We will communicate results to the treating physician so they can adjust therapy accordingly.

- Nose and throat swab: Collection of the sample can cause a short unpleasant sensation when the swab touches the mucosal lining.

- Asthma diagnostics: When the infants is sensitive to methacholine it may become a bit short of breath. The lungfunction laborant will closely monitor the child during the test.

- Time: Dependent on subgroup: confirmed wheeze(max 210 min), unconfirmed wheeze (max 180 min) healthy control (max 180 min) rest cohort (30 min).

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Age between 0 and 2 years
Informed consent from both parents / guardian

Exclusion criteria

Known metabolic, genetic or syndromal disorders
Known inflammatory diseases
Known underlying respiratory tract disease like congenital airway abnormalities, cystic fibrosis, primary ciliary dyskinesia, brunchopulmonary dysplasia or bronchiectasis.

Study design

Design

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

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2009
Enrollment:	1000
Type:	Actual

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	NL27511.018.09