Pediatric Asthma Non-invasive Diagnostic Approaches

Published: 29-03-2019
Last updated: 12-04-2024

Identify phenotypes using clinical characteristics and non-invasive biomarkers that can guide treatment.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Allergic conditions
Study type	Observational non invasive

Summary

ID

NL-OMON55765

Source
ToetsingOnline

Brief title
PANDA

Condition

- Allergic conditions
- Bronchial disorders (excl neoplasms)

Synonym
asthma, chronic airway disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breathomics, childhood asthma, phenotyping, transcriptomics

Outcome measures

Primary outcome

Differences in clinical characteristics and biomarker profiles between children

that remain difficult to treat upon standardized clinical care (based on

symptoms, exacerbations and lung function) and children that are controlled.

Secondary outcome

reduction in number of exacerbations

improvement in severe asthma questionnaire score

improvement in fatigue

unsupervised cluster analyses on the -omics data

Study description

Background summary

Pediatric asthma is a heterogeneous disease. With the emergence of novel targeted-treatments for severe pediatric asthma (such as mepolizumab), it is important to develop accurate and objective tests to discriminate between different asthma phenotypes and guide treatment

Study objective

Identify phenotypes using clinical characteristics and non-invasive biomarkers that can guide treatment.

Study design

Observational multicenter study. Children will be treated according to a standardized clinical care protocol. Addition study measurements consist of: questionnaires (to obtain patient-reported outcomes, such as fatigue and quality of life), exhaled breath measurements (in case patients report to the

hospital) and nasal brushes (during inclusion). Patients are followed for 6 months.

Study burden and risks

The burden of the children and parents is low to moderate. Collection of biosamples (exhaled breath, nasal brushes, DNA isolation from saliva) will be combined with regular clinical care visits and have a limited burden. In the future, the results of this study could lead to improved treatment for paediatric patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Between 6-17 years of age
- Doctor*s diagnosis of asthma
- Treated on asthma GINA treatment step 3 or higher
- Signed informed consent from parents (guardians) and children (when applicable)
- Dutch speaking

Exclusion criteria

Serious lung disease other than asthma (cystic fibrosis, primary ciliary dyskinesia, congenital lung disorders, severe immune disorders).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-12-2019
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	29-03-2019
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2021
Application type:	Amendment
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	NL67105.018.18