Exhaled biomarker analysis for therapy stratification in asthma (STRATA)

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1. Optimize breath collection settings for optimal use in children.2. Evaluate the use of breath biomarkers for the prediction of therapeutic response in asthmatic children.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON43274

Source
ToetsingOnline

Brief title
STRATA

Condition

- Respiratory disorders NEC

Synonym
Asthma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: asthma, children, exhaled biomarkers, therapy stratification

Outcome measures

Primary outcome

Differences in exhaled biomarker profile, between children responding to treatment and children not responding to treatment.

Secondary outcome

Target biomarker concentrations of different breath fractions of the same patient will be compared and aggregated at a group level. Assessed parameters will include the reproducibility and the breath fraction that carries the highest chemical information content, highest level of target biomarkers and allows the shortest collection time. Taking these various factors into account an optimal sampling strategy will be selected. This strategy will be used to study the secondary and main study aim.

Study description

Background summary

Asthma is the most common chronic respiratory disease in childhood. A subset of asthma patients does not reach adequate levels of control despite being on high dose treatment. These patients are responsible for a disproportionate fraction of 1) reduced school attendance and 2) asthma related deaths 3) the health costs pressurizing healthcare infrastructure. Therefore there is an urgent need to develop non-invasive diagnostic tools that match the right patient to the right treatment from the outset of their treatment. Current tests for stratification of asthma patients are not optimal. This has prevented asthma stratification from being widely implemented resulting in over- and under treatment of patients.
Previous research has revealed the existence of exhaled biomarkers (VOCs) that differentiate between various inflammatory processes in the airway. VOC*s are easily accessible candidate biomarkers for therapy stratification and response monitoring and have been shown to be applicable in asthma patient stratification.
In order to bring VOC based stratification to the clinic, standardization of

sample collection and the analysis of the VOCs is required. We recently co-developed the ReCIVA breath sampler as part of Breathe Free Open Source Breath sampler Consortium. This device enables highly standardized, quick and easy breath collection and allows targeted selection of breath fractions allowing a focus on those fractions carrying the highest concentration of target biomarkers (www.breathe-free.org).

Study objective

1. Optimize breath collection settings for optimal use in children.
2. Evaluate the use of breath biomarkers for the prediction of therapeutic response in asthmatic children.

Study design

This study is designed as a prospective cohort study integrated into clinical practice (see protocol, section 3 Methods).

Study burden and risks

Sampling of breath is extremely non-invasive. The method does not impose any resistance to inspiration or expiration. Previously this device has been validated and in addition evaluated for patient discomfort in a population of 5-7 year-old children. We found that children did not experience any discomfort while breathing in this breath sampling device. No extra visits/procedures outside breath collection will be part of this study.
The STRATA study is a low risk study that does not interfere with normal clinical treatment pathways. According to the *CRU risicoinschatting* this study has a risk of negligible risk.
We will perform clinical data monitoring, technical monitoring and monitoring of patient acceptance.

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

Asthma diagnosis: established clinician diagnosis of asthma according to GINA guidelines
Treatment: patients receiving GINA step 3,4 or 5 treatment
Age: *6 - < 18 years

Exclusion criteria

Established other pulmonary disease
Recent IMP study within 5.5 half lives of the study drug to the date of last drug administration.
Not being able to perform lung function measurements due to neurologic disease or developmental delay

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	ReCIVA breath sampler
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-11-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-12-2016
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	NL59286.018.16