Exhaled Markers in Asthma during Inhaled steroid Lowering

Published: 29-07-2011
Last updated: 28-04-2024

1. To identify breathprints of volatile organic compounds which are associated with loss of asthma control (deterioration in symptoms and lung function) after interruption of inhaled steroid therapy.2. To examine the critical VOCs of these...

Ethical review	-
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON35841

Source
ToetsingOnline

Brief title
EMAIL

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma, exacerbatie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Asthma, Exhaled breath, Inhaled corticosteroids, Loss of control

Outcome measures

Primary outcome

Change in eNose breathprint at loss of control compared to stable condition,

after completion of 8 weeks steroid withdrawal phase.

Secondary outcome

1. Individual biomarkers in sputum, blood ann exhaled breath condensate (EBC)

that are associated with asthma control and with electronic nose ann GC-MS

breathprints.

2. Hemostatic activity.

Study description

Background summary

In asthma, symptoms and lung function are only moderately associated with a change in airways inflammation, as in a period of loss of control or exacerbation. Therefore, there is a need for biomarkers that reflect inflammation more directly and that are easy to obtain. Direct on-line assessment of exhaled air volatile organic compounds (VOCs) may avoid the need of special tests in expert centres and will particularly be suitable in primary care and for the so-called poor-perceivers of exacerbation symptoms.
The current study will assess the ability of exhaled breath molecular profiling using an electronic nose and gas chromatography and mass spectrometry to discriminate breath molecular profiles (breathprints) from asthma patients during controlled and uncontrolled periods. For this purpose, an exacerbation will be induced by interruption of inhaled corticosteroids.

Study objective

1. To identify breathprints of volatile organic compounds which are associated with loss of asthma control (deterioration in symptoms and lung function) after interruption of inhaled steroid therapy.

2. To examine the critical VOCs of these breathprints in exhaled air by gas chromatography and mass spectrometry (GC-MS).
3. To identify individual biomarkers in sputum, blood and EBC that are associated with asthma control and electronic nose and GC-MS breathprints.
4. To examine the effect of loss of asthma control by interruption of inhaled steroids on haemostatic activity.
5. To examine whether there is an association between markers of coagulation, inflammation and exhaled molecular profiles assessed by electronic nose and GC-MS.

Study design

14 weeks prospective follow-up study. Reduction of clinical control and re-establishment of control will be obtained by cessation and restoration of inhaled steroids.

Intervention

Breath measurements by electronic nose platform and GC-MS and sputum and blood biomarkers will be monitored at baseline, and during withdrawal and restoration of inhaled steroids.

Study burden and risks

Patients will interrupt regular inhaled corticosteroids. This will cause a transient loss of asthma control. The model that is used in this study proved to be safe.
Direct benefits for the patients lie within the increased awareness they will get of their asthma symptoms and symptom fluctuations, which will increase the self-management of the disease.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age: at least 18 years.
- Mild to moderately severe persistent asthma according to the GINA criteria.
- Using at least a daily dose of inhaled corticosteroids (* 500 ug ICS fluticasone or equivalent).
- Controlled or partly controlled asthma according to the criteria by GINA.
- Exacerbations: one or more in the past 2 years.
- Non-smoking or stopped smoking more than 12 months ago and a total maximum of 5 pack years.
- No other clinically significant abnormality on history and clinical examination.
- Able to give written and dated informed consent prior to any study-specific procedures.

Exclusion criteria

- Change in the dose of inhaled corticosteroids within 4 weeks prior to screening.
- A course of oral corticosteroids, antibiotics or a respiratory infection within 4 weeks prior to the study.
- Use of ipratropium, anti-IgE or oral corticosteroids.
- 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: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-04-2012
Enrollment:	30
Type:	Actual

Ethics review

Not available

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	NL36067.018.11