Inflammatory subtypes in asthma.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26030

Source
NTR

Brief title
NEON

Health condition

Asthma; Eosinophilic asthma; Asthma subtypes; biomarker

Sponsors and support

Primary sponsor: Academisch Medisch Centrum (AMC) Amsterdam
Source(s) of monetary or material Support: Glaxo Smith Kline (GSK)

Intervention

Outcome measures

Primary outcome

eNose breathprint of eosinophilic and non-eosinophilic astma.

Secondary outcome

Individual biomarkers and proteomic profiles in sputum, blood, urine, and nasal lavage, associated with eosinophilic asthma and non-eosinophilic asthma.

Study description

Background summary

N/A

Study objective

1. Exhaled molecular profiling will discriminate eosinophilic asthma from non-eosinophilic asthma;

2. Exhaled molecular profiling is associated with biomarkers and proteomic profiles in sputum, blood, urine and nasal lavage.

Study design

1. Screening visit; -28 to -14 days;

2. Collection of samples; 0.

Intervention

1. Lungfunction;

2. Sputum induction;

3. Collection of exhaled air;

4. Blood withdrawal;

5. Nasal lavage;

6. Collection of urine.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age >18 years;

2. Clinical presentation of asthma;

3. Airway hyperresponsiveness, indicated by a positive methacholine challenge with PC20 □ 8 mg/ml OR;

4. Reversibility in FEV1 of ≥ 12% predicted;

5. Requiring inhaled corticosteroids at high doses (≥ 500 ug ICS fluticasone or equivalent);

6. Non-smoking or stopped smoking more than 12 months ago and 10 pack years or less;

7. No condition or treatment which may increase the risk of bleeding;

8. No other clinically significant abnormality on history and clinical examination;

9. Able to give written and dated informed consent prior to any study-specific procedures.

Exclusion criteria

1. Change in the dose of ICS in 4 weeks prior to screening;

2. A course of oral corticosteroids, antibiotics or a respiratory infection within 4 weeks prior to the study;

3. Use of anti-leukotrienes, chromoglycates, anti-cholinergics within 4 weeks prior to the study;

4. Pregnancy;

5. 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;

6. Unwillingness or inability to comply with the study protocol for any other reason.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2010
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-06-2010
Application type:	First submission

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
NTR-new	NL2238
NTR-old	NTR2364
Other	METC AMC : 09/326
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A