Infections in Stable Asthmatic Patients: Non Invasive Detection

Published: 18-08-2008 Last updated: 07-05-2024

The first aim of the study is to determine the prevalence of latent infections by non invasive assessment of induced sputum, exhaled breath condensate and nasal/throat swabs in stable asthmatic patients and controls. The second aim is to value...

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract infections
Study type	Observational invasive

Summary

ID

NL-OMON31432

Source ToetsingOnline

Brief title Infections in Stable Asthmatic Patients: Non Invasive Detection

Condition

• Respiratory tract infections

Synonym Asthma

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum **Source(s) of monetary or material Support:** University of Foggia;Italie

Intervention

Keyword: Asthma, Infections, Non Invasive

Outcome measures

Primary outcome

The first aim of the study is to determine the prevalence of latent infections

by non invasive assessment of induced sputum, exhaled breath condensate and

nasal/throat swabs in stable asthmatic patients and controls.

Secondary outcome

The severity of airway inflammation based on sputum cell differentials

Study description

Background summary

Asthma is a disease characterized by variable airflow limitation and chronic airway inflammation. There is overwhelming evidence that respiratory infections are closely associated with exacerbations of pre-existing asthma and that rhinovirus infection plays an important role. Furthermore, latent or persistent infections may be responsible for the chronicity of airway inflammation.

We postulate that:

a. Patients with stable asthma have increased presence of viruses and bacteria in the airways as compared to controls.

b. Severe asthmatic patients have a higher load of viruses and bacteria than mild asthmatic patients.

c. Infections can be detected by non invasive sampling of the airways.

d. The presence of pathogens in the airways is reproducible with non invasive techniques.

e. The persistent infections correlate with inflammatory markers measured in the same samples.

Study objective

The first aim of the study is to determine the prevalence of latent infections by non invasive assessment of induced sputum, exhaled breath condensate and nasal/throat swabs in stable asthmatic patients and controls.

2 - Infections in Stable Asthmatic Patients: Non Invasive Detection 5-05-2025

The second aim is to value whether the presence and types of bronchial pathogens are associated with clinical severity of asthma.

The third aim is to determine whether the assessment of latent infections can be reproduced after six weeks and twelve weeks from the first measurement.

The fourth aim is to investigate the associations between latent infections and airways inflammation.

Study design

The study will have a cross-sectional design, including patients with asthma and controls.

The study consists of three study phases:

1. Screening: a review of the medical history, physical examination, standard spirometry, post-bronchodilator spirometry and methacholine challenge (in case of uncertain diagnosis of asthma) will be performed.

2. Phase 1: nasal and throat swabs, breath condensate and induced sputum will be collected.

3. Phase 2 and 3: the patients will repeat all the procedures included in phase 1 after six and twelve weeks, respectively.

Screening for viral and bacterial pathogens will be done with real-time multiplex PCR on all the samples collected during the phase 1, phase 2 (after six weeks) and phase 3 (after twelve weeks).

Study burden and risks

The current tests are purposely non-invasief. (except the swabs) Sputum induction will follow a safety protocol validated in severe asthma.

Contacts

Public Academisch Medisch Centrum

Meibergdreef 9 1105 AZ Amsterdam Nederland **Scientific** Academisch Medisch Centrum

Meibergdreef 9 1105 AZ Amsterdam Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- Men and/or women age between 18-65 years

- History of episodic chest tightness and wheezing (for the MILD and SEVERE astmatic patients)

- Prebronchodilator FEV 1 *80% predicted (for the MILD asthmatic patients)
- Reversibility in FEV1>12% predicted, or documented hyperesponsiveness (PC20 methacoline < 4mg/ml) during the past 12 months.
- Steroid-naïve (for the MILD asthmatic patients)
- Non smoking or ex-smokers (stopped more than 12 months ago and 5 pack year or less).
- Proven skin prick test. (for the MILD asthmatic patients)

- Use of high doses of inhaled corticosteroids (* 1000 μ g/day beclomethasone or equivalent) and long acting bronchodilators for more than 12 months. (for the SEVERE athmatic patients)

- One severe asthma exacerbation requiring oral steroid therapy during the past 12 months. (for the SEVERE athmatic patients)

- Baseline FEV1*75% of predicted or negative documented airway hyperresponsiveness (PC20 methacoline>8mg/ml) (for the HEALTHY subjects)

- Negative history of pulmonary and any other relevant diseases. (for the HEALTHY subjects)

Exclusion criteria

- History of current alcohol or drug abuse, as judged by the investigator.

- Subjects who have had an exacerbation or a chest infection within the last 4 weeks prior to the study.

- Uncontrolled hypertension-systolic blood pressure(BP)>200 mmHg and/or diastolic BP>100 mmHg.

- Concomitant disease or condition which could 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

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2008
Enrollment:	45
Туре:	Anticipated

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.

5 - Infections in Stable Asthmatic Patients: Non Invasive Detection 5-05-2025

In other registers

Register

Other CCMO ID Is in aanvraag NL20639.018.08