Infections in stable asthmatic patients: non invasive detection

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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....

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23271

Bron
Nationaal Trial Register

Verkorte titel
NIDIA

Aandoening

Stable severe and mild asthma, respiratory tract infections.

Ondersteuning

Primaire sponsor: Academic medical Center (AMC)
Overige ondersteuning: Academic medical Center (AMC); University of Foggia (Italy)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Fifteen mild persistent asthmatic patients, fifteen severe persistent asthmatic patients, fifteen healthy, non asthmatic patients will be recruited.

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).

Doel van het onderzoek

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.

Onderzoeksopzet

The measurements take place at two visits. In addition, all the procedures will be repeted after 6 and 12 weeks, respectively.

Onderzoeksproduct en/of interventie

A review of the medical history, physical examination, standard spirometry, post-bronchodilator spirometry and/or a methacoline challenge will be performed.
The enrolled patients will undergo several procedures:

- Collection of exhaled breath condensate

- Nasopharyngeal flocked swab (NPFS)

- Throat flocked swab (TFB)

- Induced sputum.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

MILD Asthmatic patients:

1. Able to give written and dated informed consent prior to any study specific procedure

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

3. History of episodic chest tightness and wheezing

4. Prebronchodilator FEV 1 ≥80% predicted

5. Reversibility in FEV1>12% predicted, or documented hyperesponsiveness (PC20 methacoline < 4mg/ml) during the past 12 months.

6. Steroid-naïve (those patients who are currently not on corticosteroids).

7. Non smoking or ex-smokers (stopped more than 12 months ago and 5 pack year or less).

8. Proven skin prick test.

9. Clinically stable: no asthma exacerbations and no respiratory tract infections within the last 4 weeks prior to the study.

10. No other clinically significant abnormality on history and clinical examination

SEVERE Asthmatic patients:

1. Able to give written and dated informed consent prior to any study specific procedure

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

3. History of episodic chest tightness and wheezing

4. Reversibility in FEV1>12% predicted, or documented hyperesponsiveness (PC20 methacoline < 4mg/ml) during the past 12 months.

5. Use of high doses of inhaled corticosteroids (≥ 1000 µg/day beclomethasone or equivalent) and long acting bronchodilators for more than 12 months.

6. One severe asthma exacerbation requiring oral steroid therapy during the past 12 months.

7. Clinically stable: no asthma exacerbations and no respiratory tract infections within the last 4 weeks prior to the study.

8. Non smoking or ex-smokers (stopped more than 12 months ago and 5 pack year or less).

9. No other clinically significant abnormality on history and clinical examination.

HEALTHY subjects:

1. Able to give written and dated informed consent prior to any study specific procedure

2. Men and/or women age between 18-50 years

3. Non smoking or ex smokers (stopped smoking more than 12 months and 5 pack years or less).

4. Baseline FEV1≥75% of predicted or negative documented airway hyperresponsiveness

(PC20 methacoline>8mg/ml)

5. Negative history of pulmonary and any other relevant diseases

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria for all the groups are:

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

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

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

4. 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.

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2008
Aantal proefpersonen:	45

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-05-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1284
NTR-old	NTR1330
Ander register	: MEC08/165
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A