A diagnostic studie: Mannitol challenge test in patients with mild to moderate COPD

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To investigate the diagnostic value of the mannitol challenge test compared to the eosinophilic inflammation in the airways.

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

Samenvatting

ID

NL-OMON21900

Bron
NTR

Verkorte titel
Mannitolstudie

Aandoening

Mild to moderate Chronic Obstructive Pulmonary Disease (COPD)

Ondersteuning

Primaire sponsor: Dept. of Repiratory Medicine
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Overige ondersteuning: Dept. of Repiratory Medicine
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Diagnostic tests:
- Mannitol (Osmohale) challenge test (Index test).
- Sputum induction to assess the degree of airway inflammation (Reference test)

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Chronic obstructive pulmonary disease (COPD) is a disease characterised by airway inflammation. A new diagnostic for bronchial–provocation testing is the use of a dry powder of mannitol. Airway hyperresponsiveness (AHR) to inhaled mannitol is dependent on the presence of inflammatory cells and release of their mediators.

Aim:

The aim of this study is to investigate if AHR to mannitol is related with the mark-ers of inflammation and markers of inflammatory damage in induced sputum.
The secondary aim is to investigate if the mannitol challenge test (MCT) affects the sputum cell count if sputum is induced 1 hour after this test.

Methods:

Twenty-three patients with mild to moderately severe COPD (GOLD stage I/II) will be included.

The mannitol challenge test (MCT) will be performed and induced sputum will be collected on two separate days with a time interval of at least 7 days. Total and dif-ferential cell counts, levels of soluble markers of inflammation (myeloperoxidase, eosinophil cationic protein, tryptase) and markers of inflammatory damage (alfa-2- macroglobuline, albumine) in whole sputum samples will be related to airway hy-perresponsiveness (AHR) to mannitol.

Doel van het onderzoek

To investigate the diagnostic value of the mannitol challenge test compared to the eosinophilic inflammation in the airways.

Onderzoeksopzet

Day 1: Indextest and the reference test.

Day 2: reference test.
Time interval between day 1 and day 2 is 1-2 weeks.

Onderzoeksproduct en/of interventie

No therapeutic intervention, only DIAGNOSTIC tests. The indextest and the referencetest will both be assessed in a group of patients.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

1. Diagnosis of COPD conform the diagnostic criteria of the Global Initiative for Obstructive Lung Disease for stage I or II (mild to moderate) COPD www.goldcopd.org.

2. Age > 40 years

3. Have post-bronchodilator FEV1 > 1,5 liters and at least 50% of predicted for height, age and gender conform the ERS normal value (see appendix 1 for formula).

4. Smoking history > 20 pack-year*

5. Current smokers as well as ex-smokers.

6. As determined by the investigator, are capable and willing to:

- perform all of the techniques necessary to measure lung function

- administer the dry powder mannitol

7. Are capable of, and have given informed consent to participate in the study.

8. The subject must be in stable clinical condition at the time of, and for a period of 14 days prior to, their recruitment into the study. Stable clinical condition is defined as lack of:

- change in sputum production (volume, color, consistency);

- increased cough;

- worsening dyspnoea;

- increased malaise, fatigue or lethargy;

- reduction in exercise tolerance;

- fever;

- antibiotic treatment (for respiratory infection).

9. No use of oral or inhaled corticosteroids 4 weeks before the first visit.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Subjects receiving treatment with inhaled corticosteroids of oral corticosteroids within the last 4 weeks.

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

3. Subjects who receiving antibiotic treatment for respiratory infection.

4. Known diagnosis of asthma or allergic rhinitis.

5. Myocardial infarction in the six months prior to enrolment.

6. Cerebral vascular accident in the six months prior to enrolment.

7. Ocular surgery in the three months prior to enrolment.

8. Active tuberculosis (TB).

9. Lung cancer or any other malignancies, which are considered by the investigator as a contraindication to participating in the study.

10. Lung disease other than COPD

11. Uncontrolled insulin-dependent or non-insulin dependent diabetes.

12. Inability to obtain informed consent from the subject or subject’s authorized representative.

13. Known intolerance to mannitol.

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

15. Have had major abdominal or chest surgery in the three months prior to enrolment.

16. Have known cerebral, aortic or abdominal aneurysm.

17. Subjects receiving treatment with béta-blockers.

18. Pregnancy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-09-2007
Aantal proefpersonen:	23
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-04-2008
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	NL1238

Register	ID
NTR-old	NTR1283
Ander register	MEC AMC : 07/215
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A