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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21900

Source
NTR

Brief title
Mannitolstudie

Health condition

Mild to moderate Chronic Obstructive Pulmonary Disease (COPD)

Sponsors and support

Primary sponsor: Dept. of Repiratory Medicine
Academic Medical Center
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P.O. Box 22700
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Source(s) of monetary or material Support: Dept. of Repiratory Medicine
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Intervention

Outcome measures

Primary outcome

Diagnostic tests:

- Mannitol (Osmohale) challenge test (Index test).

- Sputum induction to assess the degree of airway inflammation (Reference test)

Secondary outcome

- Influence of the mannitol challenge test on induced sputum (repeatability)

- exhaled nitric oxide (NO) measured according to the ATS recommendations.

- serum inflammatory proteins: albumin, alpha2 macroglobulin, Luminex assay.

- Electronic nose: the Cyranose 320. A vital capacity volume is analyzed as smell print.

- GC-MS: gas chromatography and mass spectrometry of breath samples (Philips Medical Research, Eindhoven, The Netherlands).

Study description

Background summary

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.

Study objective

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

Study design

Day 1: Indextest and the reference test.

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-09-2007
Enrollment:	23
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-04-2008
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	NL1238
NTR-old	NTR1283
Other	MEC AMC : 07/215
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A