

# Mannitol inhalations as a new procedure for testing of airways hyperresponsiveness

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1. To test feasibility of mannitol inhalations in a Dutch pulmonary out-patient clinic.2. To compare time and costs involved in measuring airways hyperresponsiveness by methacholine to mannitol

|                              |                                      |
|------------------------------|--------------------------------------|
| <b>Ethical review</b>        | Approved WMO                         |
| <b>Status</b>                | Recruitment stopped                  |
| <b>Health condition type</b> | Bronchial disorders (excl neoplasms) |
| <b>Study type</b>            | Interventional                       |

## Summary

### ID

NL-OMON31934

### Source

ToetsingOnline

### Brief title

Mannitol en AHR

### Condition

- Bronchial disorders (excl neoplasms)

### Synonym

Bronchial hyperreactivity, chronic bronchitis, COPD, reaction of airways to stimuli that do not cause a reaction normallyhma

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Longziekten

**Source(s) of monetary or material Support:** bedrijf,Pharmaxis

## Intervention

**Keyword:** Airway hyperresponsiveness, Mannitol, Metacholine

## Outcome measures

### Primary outcome

Time involved in measurement of hyperresponsiveness (including technician time for preparation and cleaning)

### Secondary outcome

- Patient reported side effects
- Patient preference
- Technician preference
- Borg score during test
- BHR questionnaire (van der Molen 2005)

## Study description

### Background summary

Airway hyperresponsiveness (AHR) is an exaggerated increase in airflow limitation following exposure to a non allergic stimulus. This can be tested with either direct or indirect challenges.

The two typical examples of bronchoconstrictor agents for direct airway challenges are histamine and methacholine. Cold air, dry air, and exercise challenge tests all measure AHR in an indirect way. Examples of bronchoconstrictor agents that are used for indirect challenges include hypotonic saline, hypertonic saline, AMP and mannitol.

The response to indirect stimuli as mannitol and AMP seems to be closely related to airway inflammation and therefore may be a better suited to assess therapeutic efficacy than direct challenges or patient reported symptoms.

Direct challenges are time consuming for site personnel and for patients.

Challenges with mannitol, a dry powder sugar alcohol, cost only 1.5 minutes per dosing step and should therefore be quicker than methacholine, the current gold standard, which takes 5 minutes per dosing step. Also the preparation time

should be shorter with mannitol.

### **Study objective**

1. To test feasibility of mannitol inhalations in a Dutch pulmonary out-patient clinic.
2. To compare time and costs involved in measuring airways hyperresponsiveness by methacholine to mannitol

### **Study design**

The study is a randomised single blinded (patient blinded), cross-over study

### **Intervention**

In random order two airway hyperreactivity test, methacholine and mannitol, separated by at least 3 days.

### **Study burden and risks**

Patients will have to come in one extra time for measuring of AHR and will be asked to fill out a number of questionnaires, this will take approximately 3 hours. Some of the patients medication will have to be stopped for a certain amount of time (maximum of three days).

There are a number of side effect reported for AHR tests, namely cough, nausea, wheezing, mild dyspnea and chest tightness. Serious adverse events have not been reported.

## **Contacts**

### **Public**

Selecteer

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Asthmatics:

- Episodic symptoms of dyspnea, and/or wheezing, and/or cough
- Allergic or non-allergic
- non current smokers (> 0.5 years)
- PC20 MCh < 8 mg/ml; COPD patients:
- Age > 40 yrs
- Active or former smokers, with a smoking history of more than 10 packyears
- Continuous symptoms of cough/sputum and/or dyspnea on exertion
- No history of asthma
- FEV1/FVC < 70 % and FEV1 between 50 and 80 % pred.; Controls
- No history of asthma or COPD
- PC20 MCh > 8 mg/ml
- FEV1/FVC > 70 % and FEV1 > 90 %pred.

### **Exclusion criteria**

m- Age < 18 years

- Inability to perform acceptable-quality spirometry or to understand directions given by personnel
- Severe airflow limitation (FEV1 < 50% of predicted or < 1.0 L)
- Heart attack or stroke in last 6 months
- Uncontrolled hypertension, systolic BP > 200, or diastolic BP > 100
- Known aortic aneurysm
- Pregnancy
- Nursing mothers
- Current use of cholinesterase inhibitor medication (for myasthenia gravis)

## Study design

### Design

|                     |                               |
|---------------------|-------------------------------|
| Study type:         | Interventional                |
| Intervention model: | Crossover                     |
| Allocation:         | Randomized controlled trial   |
| Masking:            | Single blinded (masking used) |
| Control:            | Active                        |
| Primary purpose:    | Diagnostic                    |

### Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 15-08-2008          |
| Enrollment:               | 120                 |
| Type:                     | Actual              |

### Medical products/devices used

|               |          |
|---------------|----------|
| Product type: | Medicine |
| Brand name:   | Aridol   |
| Generic name: | mannitol |

## Ethics review

|                    |   |
|--------------------|---|
| Approved WMO       |   |
| Application type:  | First submission  |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## 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                     |
|----------|------------------------|
| EudraCT  | EUCTR2006-003795-35-NL |
| CCMO     | NL22652.042.08         |