# Mannitol inhalations as faster procedure for testing of airways hyperresponsiveness.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON21125

**Source**
NTR

**Brief title**
N/A

**Health condition**

Asthma, COPD, subjects without airways hyperresponsiveness

### Sponsors and support

**Primary sponsor:** Department of Respiratory Medicine
University Medical Center Groningen
Postbox 30.001
9700RB Groningen
the Netherlands
**Source(s) of monetary or material Support:** Pharmaxis Ltd.
2/10 Rodborough Rd, Frenchs Forest NSW 2086
Australia

### Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

1. Patient reported adverse events.

2. Patient preference.

3. Technician preference.

4. Borg score during test.

5. Exhaled breath condensate (EBC).

6. Bronchial Hyperreactivity questionnaire (BHR, van der Molen 2005)

# Study description

### Background summary

Airway hyperresponsiveness (AHR) can be measured with direct (histamine or methacholine) and indirect agents (AMP, hypertonic saline, excercise and mannitol). We believe that measurement of airways hyperresponsiveness by mannitol (Aridol©) as compared to methacholine saves time to the lung function technician, while being as sensitive to discern hyperresponsive from normo-responsive. We will assess the saved time in this randomised, single-blinded, cross-over study.

### Study objective

Measurement of airways hyperresponsiveness by mannitol (Aridol©) as compared to methacholine saves time to the lung function technician, while being as sensitive to discern hyperresponsive from normo-responsive, and being at least equally acceptable to patients presenting at a pulmonary out-patient clinic.

### Study design

N/A

**Intervention**

Measurement of bronchial hyperresponsiveness with mannitol and methacholine.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Asthmatics:

1. Episodic symptoms of dyspnea, and/or wheezing, and/or cough.

2. Allergic or non-allergic.

3. non current smokers (> 0.5 years).

4. PC20 MCh < 8 mg/ml

COPD patients:

1. Age > 40 yrs.

2. Active or former smokers, with a smoking history of more than 10 packyears.

3. Continuous symptoms of cough/sputum and/or dyspnea on exertion.

4. No history of asthma.

5. FEV1/FVC < 70 % and FEV1 between 50 and 80 % pred.

Controls:

1. No history of asthma or COPD;

2. PC20 MCh > 8 mg/ml;

3. FEV1/FVC > 70 % and FEV1 > 90 %pred.

### Exclusion criteria

1. Age < 18 years.

2. Inability to perform acceptable-quality spirometry or to understand directions given by personnel.

3. Severe airflow limitation (FEV1 < 50% of predicted or < 1.0 L).

4. Heart attack or stroke in last 3 months.

5. Uncontrolled hypertension, systolic BP > 200, or diastolic BP > 100.

6. Known aortic aneurysm.

7. Pregnancy.

8. Nursing mothers.

9. 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 |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2007 |
| Enrollment: | 120 |
| Type: | Actual |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 29-08-2006 |
| 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 | NL746 |

| Register | ID |
| --- | --- |
| NTR-old | NTR756 |
| Other | : Griac001 |
| ISRCTN | ISRCTN72604310 |

# Study results

**Summary results**
Planned