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# Mannitol inhalations as faster procedure for testing of airways hyper-responsiveness

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 22/11/2006 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 22/11/2006 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 28/11/2006 | Respiratory | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
Griac001

## Study information

**Scientific Title**

## Study objectives
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.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Medisch Ethische Toetsingscommissie Universitair Medisch Centrum Groningen (Medical Ethical Committee University Medical Center Groningen), approval received on October 3rd 2006.

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Asthma, Chronic Obstructive Pulmonary Disease (COPD)

## Interventions
Measurement of bronchial hyper-responsiveness with mannitol and methacholine.

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Mannitol and methacholine

## Primary outcome(s)
Time involved in measurement of hyper-responsiveness (including technician time for preparation and cleaning).

## Key secondary outcome(s)
1. Patient reported adverse events.
2. Patient preference.
3. Technician preference.
4. Borg score during test.
5. Exhaled Breath Condensate (EBC).
6. Bronchial Hyper-Reactivity questionnaire (BHR)

## Completion date

31/08/2007

# Eligibility

### Key inclusion criteria
Asthmatics:
1. Episodic symptoms of dyspnea, and/or wheezing, and/or cough
2. Allergic or non-allergic
3. Non current smokers (more than 0.5 years)
4. Provocation Concentration that causes a decrease in forced expiratory volume in one second of 20% (PC20) for MethaCholine (MCh) less than 8 mg/ml

Chronic Obstructive Pulmonary Disease (COPD) patients:
1. Age more than 40 years
2. Active or former smokers, with a smoking history of more than ten pack years
3. Continuous symptoms of cough/sputum and/or dyspnea on exertion
4. No history of asthma
5. Forced expiratory volume in one second (FEV1)/Forced Vital Capacity (FVC) less than 70% and FEV1 between 50 and 80% predicted

Controls:
1. No history of asthma or COPD
2. PC20 MCh more than 8 mg/ml
3. FEV1/FVC more than 70% and FEV1 more than 90% predicted

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Not Specified

### Key exclusion criteria
1. Age less than 18 years
2. Inability to perform acceptable-quality spirometry or to understand directions given by personnel
3. Severe airflow limitation (FEV1 less than 50% of predicted or less than 1.0 L)
4. Heart attack or stroke in last three months
5. Uncontrolled hypertension, systolic Blood Pressure (BP) more than 200 mmHg, or diastolic BP more than 100 mmHg
6. Known aortic aneurysm
7. Pregnancy
8. Nursing mothers
9. Current use of cholinesterase inhibitor medication (for myasthenia gravis)

### Date of first enrolment

01/09/2006

**Date of final enrolment**
31/08/2007

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Head Department of Respiratory Medicine**
Groningen
Netherlands
9700 RB

# Sponsor information

**Organisation**
University Medical Center Groningen (UMCG) (The Netherlands)

**ROR**
https://ror.org/03cv38k47

# Funder(s)

**Funder type**
Industry

**Funder Name**
Pharmaxis Ltd.

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration