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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	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 respons to indirect stimuli as mannitol and AMP seems to be closely related to airway inflammation and therefore may be a better suited to asses 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, wich 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 quesionnaires, 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

Hanzeplein 1
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Scientific
Selecteer

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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