ISRCTN72604310 https://doi.org/10.1186/ISRCTN72604310

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Time involved in measurement of hyper-responsiveness (including technician time for preparation and cleaning).

Secondary outcome measures
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)

Overall study start date
01/09/2006

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

Age group
Adult

Sex
Not Specified

Target number of participants
120

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)

Sponsor details
Department of Respiratory Medicine
P.O. Box 30001
Groningen
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Industry

Funder Name
Pharmaxis Ltd.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration