Validation of a new protocol for the methacholine provocationtest in patients with hyper-reactive airways.

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The aim of this study is to compare the PD20 values measured with the Vilbiss 646 jet nebulizer protocol and with the MedicAid nebulizing protocol in 20 subjects with respiratory symptoms suggestive of bronchial hyperreactivity.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON35238

Source
ToetsingOnline

Brief title
METHA2-study

Condition

- Bronchial disorders (excl neoplasms)

Synonym
airway hyper-responsiveness, increased sensitivity of the airways

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Afdeling Longgeneeskunde

Intervention

Keyword: Asthma, Bronchial hyperreactivity, Bronchial provocation test, Methacholine

Outcome measures

Primary outcome

The severity of AHR can be expressed in de amount of metacholine dosage in

miligram that causes a 20% fall in FEV1, known as the PD20.

Secondary outcome

Not applicable

Study description

Background summary

Bronchial provocation tests (BPTs) are used to detect the presence and severity of airway hyperresponsiveness (AHR) in patients with respiratory symptoms that are suspected of having asthma. In these tests nebulized methacholine is administered to a subject until a fall in forced expiratory volume in one second (FEV1) >= 20% is established. The severity of airway hyper-responsiveness can be expressed as the dose of methacholine that causes a 20% fall FEV1, known as the PD20.

Several methods to administer methacholine are currently available. In the dosimeter method, methacholine is inhaled during a specific number of deep breaths. Our department now uses the aged DeVilbiss 646 jet nebulizer in combination with nebulization schema of increasing concentrations. New techniques like the MedicAid jet nebulizer are used in combination with a dosage schema of increasing number of puffs with a constant concentration. By validating the new nebulization technique is the pulmonary medicine department able to switch to a new nebulizer device for the future BPTs, which offers a more effective way of obtaining and processing data.

Study objective

The aim of this study is to compare the PD20 values measured with the Vilbiss 646 jet nebulizer protocol and with the MedicAid nebulizing protocol in 20 subjects with respiratory symptoms suggestive of bronchial hyperreactivity.

Study design

The design of this study will be a single randomised crossover centre study at the Medisch Spectrum Twente, Enschede.

Intervention

Participating subjects will perform two times a bronchial provocation test (BPT). Subjects will be randomly divided into two groups. Group one will measure first with the DeVilbiss 646 jet nebulizer and then with the MedicAid jet nebulizer. In the other group is the nebulizer order reversed.

Study burden and risks

A bronchial provocation test can induce some respiratory symptoms, such as coughing, hoarseness and shortness of breath. This however, is the concept of the BPT so that the severity of AHR could be evaluated. To treat respiratory symptoms caused by metacholine induced bronchospasmes, a bronchodilator is given at the end of the provocation test. A subject will leave the deparment afther the test without serious complains. The risk for adverse events in this study is negligible. The currently used provocation protocol is conducted for years without occurrence of any (serious) adverse events. The new nebulizer protocol follows the same safety procedures as the known DeVilbiss 646 jet nebulizer protocol. The cumulated dosage metacholine is of the same amount with both nebulizers. The amount of metacholine is calculated with the known histamine protocol and is expressed on molar base.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age >= 18 years.
Symptoms off bronchial hyper-reactivity.
Positive provocation test (PD20).

Exclusion criteria

Recent use of oral or inhaled bronchodilators
Severe airways obstruction at baseline (FEV1 < 1.2 liter)
FEV1 < 50% of the reference value
Recent myocardial infarction (< 3 months)
Recent cerebral vascular accident (< 3 months)
Known arterial aneurysmata
Inability to understand the procedures and the implication of a challenge test
Spirometry-induced airway obstruction
Moderate to severe airway obstruction (e.g. predicted value: male: predicted FEV1 minus 1.5 liter or female: predicted FEV1 minus 1.2 liter)
FEV1 < 65% of the reference value and FEV1 < 2 liter
Recent upper respiration tract infection (< 2 weeks)
During exacerbation of asthma
Hypertension: systolic blood pressure > 200 mmHg or diastolic pressure > 100 mmHg
Pregnancy
Epilepsia dependent on medication

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-06-2010
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Spirometry
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	07-06-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
CCMO	NL29255.044.09