Differences in small airways disease between asymptomatic and symptomatic subjects with airway hyperresponsiveness

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To investigate the presence and extent of small airways disease in subjects with asymptomatic AHR, patients with asthma and non-AHR controls. Specific research questions:1) Do subjects with asymptomatic AHR have less small airways disease than...

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

Summary

ID

NL-OMON37837

Source
ToetsingOnline

Brief title
AHR and small airways

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma, oversensitive airways

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: airway hyperresponsiveness, asthma, asymptomatic, Small airways

Outcome measures

Primary outcome

peripheral airway resistance, measured with IOS

Secondary outcome

Peripheral airway resistance measured with IOS during provocationtest

Other small airways parameters:

- FEF25-75

- alveolar NO

- RV, RV/TLC

mRNA expression in nasal epithelium.

Study description

Background summary

Bronchial hyperresponsiveness (BHR) is a feature of asthma. There are also persons with asymptomatic BHR. These people do not experience symptoms, however earlier research indicates that these subjects have increased inflammation and remodelling of the airways. Furhtermore, asymptomatic BHR appears to be a risk factor for asthma development. Recently, there has been increasing evidence that dysfunction of the small airways (defined as airways with an internal diameter >2 mm) contributes importantly to airflow obstruction and symptoms in patients with asthma. We hypothesize that asymptomatic subjects with BHR do not experience respiratory symptoms because they have less small airways disease

compared to symptomatic subjects.

Study objective

To investigate the presence and extent of small airways disease in subjects with asymptomatic AHR, patients with asthma and non-AHR controls.

Specific research questions:
1) Do subjects with asymptomatic AHR have less small airways disease than patients with asthma?
2) Do subjects with asymptomatic AHR have more small airways disease than healthy non-AHR controls?

Study design

An observational study, comparing 3 groups:
- Asthmatics
- Subjects with asymptomatic AHR
- Healthy controls without AHR

Pulmonary function will be measured, as well as a provocation test with methacholine during which dyspnea and IOS will be measuren

Study burden and risks

The burden shall be very limited for the patients. The study will take about 4 hours, divided over 2 visits. The risks are also limited. During the provocation test, the subject may experience some dyspnea. The nasal brush may cause a nosebleed.

This study may give insight into the origin of symptoms in ashtma en the association between these symptoms and small airways disease. This knowledge can be used to better treat asthma patients, e.g. with medication designed to target the small airways.

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

Inclusion criteria for asymptomatic subjects without AHR :
• Age between 18 and 65 years.
• FEV1 > 80% predicted post bronchodilator.
• PC20 methacholine <= 8 mg/ml.
• No history of asthma or previous use of asthma medication.;Inclusion criteria for asymptomatic subjects without AHR :
• Age between 18 and 65 years.
• FEV1 > 80% predicted post bronchodilator.
• PC20 methacholine >8 mg/ml.
• No history of asthma or previous use of asthma medication.;Inclusion criteria for patients with asthma:
• Age between 18 and 65 years.
• FEV1 > 80% predicted.
• PC20 methacholine <=8 mg/ml.
• Doctor's diagnosis of asthma
• No history of COPD

Exclusion criteria

• Use of inhaled or oral steroids, antihistamines, nedocromil, theophylline, leukotrien antagonists or long-acting beta-agonists for at least three weeks before the start of the

study.
• Any disease that may affect the outcome of the study as judged by the Investigator.
• FEV1 <1.2 liter.
• A respiratory tract infection within 4 weeks prior to the start of the study.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-05-2012
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	16-05-2012
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
CCMO	NL40013.042.12
Other	volgt