Small Airway function in obesity and asthma study

Published: 11-04-2016
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The aims of the current study are to compare available tests for small airway function in asthmatic patients and to assess differences in small airway function between obese and non-obese asthmatic patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational invasive

Summary

ID

NL-OMON45982

Source
ToetsingOnline

Brief title
SANTANA

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
asthma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Chiesi Farmaceutici,Chiesi Pharmaceuticals S.p.A.;Italy

Intervention

Keyword: airways, asthma, obesity, overweight

Outcome measures

Primary outcome

Compare available tests for small airway function in asthmatic patients. The primary endpoint is Impulse Oscillometry.

Secondary outcome

Other small airway measurements:

- spirometry
- multiple breath nitrogen washout
- body plethysmography
- RGA Single breath CO-diffusion (TLCO, KCO, VA)
- fraction exhaled nitric oxide

Other airway tests

- methacholine provocationtest
- eosinophils in sputum en blood

Questionnaires:

- Asthma control
- Bronchial hyperreactivity
- Asthma specific quality of life
- Small Airway Disease

- Medication adherence

Study description

Background summary

Overweight and obesity has reached epidemic proportions. In 2014, 600 million adults were obese. Obesity is a risk factor for multiple chronic diseases, including asthma. Prospective studies identified an increased odds of 1.51 to develop asthma at 1 year follow-up in overweight or obese individuals compared with normal weight individuals. This translates into 250.000 new adult cases of asthma each year in the United States attributable to overweight and obesity. Additionally, obese asthmatic patients have lower quality of life and worse symptom control than non-obese asthmatic patients. Traditionally asthma is considered an obstructive disease of the large airways. However, current evidence shows that asthma affects the whole respiratory tract, including the airways with a diameter less than 2 millimeter. Because the contribution of these small airways to lung resistance is minimal, they were historically called the *quiet zone*. However, these small airways account for 98.8% of the total lung volume and in asthma patients small airway dysfunction is clearly associated with worse symptom control and higher number of exacerbations. Recent studies in obese asthmatic patients showed that weight loss improves asthma symptoms. Interestingly, a simultaneous improvement in small airway function was observed. So, asthma in obese patients is associated with worse small airway function. This could be of clinical importance for obese asthmatic patients, as extra-fine inhalation medication is available to target this compartment of the lung. Yet, no gold standard exists to assess small airway function and previous studies only used a minority of the available tests. Additionally, only a few studies compared differences in small airway function in obese and non-obese individuals. Until now, no study directly compared several tests to assess small airway function in asthmatic patients with or without obesity.

Study objective

The aims of the current study are to compare available tests for small airway function in asthmatic patients and to assess differences in small airway function between obese and non-obese asthmatic patients.

Study design

Cross-sectional

Study burden and risks

Participants will visit the study center three times, each time 2 hours. During these visits, lung functions tests are performed. Questionnaires of 17 pages are administered to participants. During the lung function tests, participants can experience light dyspnoea. They will be administered a bronchodilator, which quickly relieves the dyspnoea. After the tests they could experience some soreness of the throat or cough. The lung function tests are a burden, but without risks.

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 who have signed informed consent form prior to the start of the study
* Clinical diagnosis for * 6 months of asthma
* Stable asthma: on a stable dose of asthma inhalation medication for at least 8 weeks prior to baseline visit
* Obese (BMI >30) or non-obese (BMI <30)

Exclusion criteria

* Change of asthma inhalation medication in the past 8 weeks before visit 1
* Asthma exacerbation (defined as use of oral or intravenous corticosteroids and/or antibiotics) in the past 8 weeks before visit 1
* Smokers: current * 10 cigarettes per day or *10 pack years
* Diagnosis of COPD
* Pregnancy, as reported by the participant
* Clinical or functional uncontrolled respiratory- or other disease that might, in the judgement of the investigator, comprise the results or interpretation of the study
* Current- or less than 1 month from baseline participation in interventional clinical trial with inhalation drugs
* Inability to comply with study procedures

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-04-2018
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	11-04-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	01-12-2017
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23609
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54867.058.15
OMON	NL-OMON23609