Expiratory airflow limitation in subjects with obesity

Published: 30-06-2008
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Objective: To investigate posture dependent small airway obstruction in subjects with obesity. To study the capacity of FOT as a measurement tool for small airways obstruction.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON32007

Source
ToetsingOnline

Brief title
Obesity and EFL

Condition

- Respiratory disorders NEC

Synonym
obesity overweight

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Foreest Instituut Alkmaar

Intervention

Keyword: Obesity FOT spirometry EFL

Outcome measures

Primary outcome

FEF25-75/FVC

mid inspiratory Xrs minus mid expiratory Xrs at 8 Herz (cmH20.s/L)

Secondary outcome

Spirometry: FEV1(L), FVC(L), IC(L), VC max(L),

Helium rebreathing: FRC, ERV, TLC

Body plethysmography: Pressure-flow loop

Forced oscillation technique: Rrs-8 (cmH20.s/L)

Frequence dependency

Resonance frequency

Baseline Xrs, Rrs

Anthropometrical data

Study description

Background summary

Obesity is a cause of dyspnea due to mechanical impairment of pulmonary ventilation. One of the causes of this impairment is expiratory flow limitation, which is related to decreased lung volume. As a result, obesity can cause an asthma-like symptoms. Therefore, some patients with obesity are misdiagnosed as asthma-patients, and treated with asthma medication. The effects of bronchodilators on the mechanical airway obstruction in obese subjects have not been well established.

Posture also has effect on lung volumes: they are decreased in supine position. Therfore, the interaction of obesity and supine posture might result in a larger decrease in lung volumes, and thereby a more increased airflow limitation. It has been suggested that both obesity and supine posture result in an obstruction of peripheral airways. Such an obstruction can be measured by spirometry, using the ratio of forced expiratory flow between 25 and 75% and

vital capacity. This measure is highly variable, however.
The forced oscillation technique (FOT) is a non-invasive method to measure the resistance and reactance of the respiratory system. Particularly the reactance has been shown useful in the measurement of airflow limitations.

We hypothesize that obesity causes a posture dependent end- expiratory airflow limitation due to a mechanical compression of lung tissue, resulting in increased resistance and reactance in the airways. Therefore, we expect no protective effect of bronchodilation by salbutamol. We expect that reactance measured by FOT detects differences in airflow limitation and correlates with airflow limitation as measured by spirometry.

Study objective

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Study design

Observational research without invasive measurements (see flowchart pag 11)

Study burden and risks

Participating in this study is low risk. Spirometry, body plethysmography and helium rebreathing are standard diagnostic tests performed in the pulmonary function test department. No extra risk is foreseen in this study. Forced oscillation technique is not (yet) a standard diagnostic test. It is a non-invasive test. No adverse events are foreseen due to this test. Benefit is an improvement in the assessment of bronchial obstruction with a technique that does not require patient cooperation and can be applied in situations where the patient really has complaints. Benefit could be improvement in diagnostics in patients with obesity, saving unnecessary treatment with inhaled medicaments.

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 obese population:;Male/female, age 25-60
BMI (body mass index) 30-40 kg/m2
Non or ex smokers with < 10 packyears;Inclusion criteria control population:;Male/female, age 25-60
BMI (body mass index) 18.5-25 kg/m2
Non or ex smokers with <10 packyears

Exclusion criteria

asthma
COPD (FEV1/IVC<0.70)
reversibility >9% in FEV1 (400 microgram salbutamol)
other significant neuromuscular, cardiac or lung disease;Exclusie criteria controle population:
asthma
COPD (FEV1/FVC<70)
any other significant neuromuscular, cardial of pulmonary disease
reversibility >9% in FEV1 (400 microgram salbutamol);Exclusion criteria control population:
No asthma
No COPD (FEV1/FVC<70)
No other significant neuromuscular, cardiac or lung disease
No reversibility >9% in FEV1 (400 microgram salbutamol)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-07-2008
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	30-06-2008
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL21919.094.08