Is the hypercapnic ventilatory respons in combination with the upper airway resistance of predictive value in COPD patients for having an OSAS?

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First question:The first aim of this study is to test the following hypothesis:Is the hypercapnic ventilatory respons in combination with the upper airway resistance of predictive value for the risk of COPD patients to have an OSAS?The second…

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

Summary

ID

NL-OMON30911

Source
ToetsingOnline

Brief title
Predictive value HCVR en UAR for having an OSAS in COPD patients

Condition

- Bronchial disorders (excl neoplasms)

Synonym
overlap syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: intern wetenschappelijk fonds

Intervention

Keyword: COPD, Hypercapnic ventilatory response, OSAS, Overlap syndrome

Outcome measures

Primary outcome

HCVR

Upper airway resistance

Secondary outcome

kind of apnoe

Study description

Background summary

Both obstructive sleep apnoea syndrome (OSAS) and chronic obstructive pulmonary disease (COPD) are common diseases in the general population (2,3). Recent epidemiological studies have shown that in developed countries the prevalence of OSAS is about 4% of males and 2% of females in the age span of 30-60 years, while COPD affects as much as 10% of the population above 30 years (7,13). Previous studies reported prevalences of an airway obstruction in patients with OSAS of 11- 41 % (12). In a study population of patients presented with COPD the prevalence of OSAS was 10-15 % (12,13,23). These data suggest that an overlap syndrome, first defined by Flenley to describe the association of OSAS (apneu/hypopneu index > 20/hr) with COPD (FEV1/VC ratio < or = 70%), is widely under diagnosed. One of the reasons for this may be the fact that in patient with COPD the symptoms of their pulmonary disease mask the OSAS symptoms. All healthy humans hypoventilate to a significant degree during normal sleep and have diminished HCVR due to mechanical impairment. It is assumed that central CO2 chemosensitivity remains unchanged (1,26).
De Backer et al have shown an increase in HCVR in patients with an overlap syndrome and in normocapnic OSAS. In severe COPD however, chronic hypercapnia is known to decrease CO2 chemosensitivity resulting in a diminished HCVR (1,6,24,25,27).
We hypothesize that a diminished HCVR at rest is protecting against having an OSAS. We postulate that patients with a mild COPD (FEV1 50-80%) and a normal or increased HCVR are at risk for developing an OSAS.

A recent human study showed that circulating leptin, an adipocyte-derived hormone,was elevated in hypercapnic patients and in patients with OSAS (14,15,16,17). Recent animal studies suggest that leptin may be a powerfull respiratory stimulant most likely by stimulation of central respiratory control systems (HCVR) (15). Since we assume that COPD patients at risk for an overlap syndrome have a normal or increased HCVR, we presume that they will have an increased circulating leptin.
(Since there is a relationship between the decrease in leptin level and the degree of improvement of nocturnal respiration, leptin could be a usefull parameter for follow up (18,19).)
It is known that eucapnic OSAS patients have an increased airway resistance, measured by IOS, only in supine position (20,21,22). We therefore think that IOS is helpful in detecting the patients with COPD at risk for an OSAS. Mainly by discriminating the upper airway resistance from the resistance in the lower airways.

Study objective

First question:
The first aim of this study is to test the following hypothesis:Is the hypercapnic ventilatory respons in combination with the upper airway resistance of predictive value for the risk of COPD patients to have an OSAS?
The second question:
Is there a difference in the beginning of the apnoe between the OSAS en overlap group?

Study design

There will be three groups of 27 patients selected. Patients will be included from out patients clinic.
One group will contain COPD Gold classification 2 or 3 , one group patients with overlap syndrome en the third group will contain patients with OSAS.
For the first question the COPD group will be compared with the overlap group to test the following hypothesis:
The HCVR and the UAR can predict the risk of a COPD patient to have an OSAS. We expect the following differences:
-The HCVR is significant higher in the overlap population than in the COPD group.
-The UAR measured by IOS and bodybox is significant higher in the overlap group.
For the second question the OSAS group will be compared with the overlap group to test the following hypothesis:
The origin of an apnoe in a patient with overlap syndrome is significant more central in comparison with the OSAS group.

The following investigations will be done:
-HVCR

-Lungfunction
-IOS
-Arterial bloodgas
-Leptine
-Questionnaires: ESS/Qol-RIQ, questions about professional situation
-polysomnography (somno-medics)
-weight, height, BMI, impedance measurement

Study burden and risks

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Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
5623 EJ Eindhoven
Nederland
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
5623 EJ Eindhoven
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

male
age 45-75 year
COPD with FEV1 30> <80% and FEV1/FVC <70%
OSAS AHI > 15
15 pack years
BMI > 25
ESS > 12

Exclusion criteria

Female
Cardiac failure

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	81
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-11-2007
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL18516.060.07