Screening for sleep apnea using home recording of the double-loop gain as a measure of periodic breathing

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Primary objectives:1. To determine the DLI threshold with optimal sensitivity and specificity. The DLI threshold is the DLI value above which the test is considered positive (and below which the test is considered negative). The optimal DLI...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON31904

Source
ToetsingOnline

Brief title
Sleep apnea and periodic breathing

Condition

- Sleep disturbances (incl subtypes)

Synonym
Sleep Apnea Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: stichting pulmoscience

Intervention

Keyword: periodic breathing, screening, sleep apnea

Outcome measures

Primary outcome

Area under the ROC-curve for DLI

Secondary outcome

not applicable

Study description

Background summary

Sleep apnea syndrome (SAS) is caracterized by repetitive events of apnea and hypopnea, usually accompanied by snoring, disturbed sleep and excessive daytime-sleepiness. These events are often part of a periodic breathing pattern, in which relative hyperventilation is followed by apnea or hypopnea. In this pattern ventilation and oxygen saturation usually oscillate with a period of 30 - 60 seconds.
Recently we described the *double-loop gain* of the respiratory control system as a measure of periodic breathing. This is a frequency-dependent variable which describes 1) the tendency of the respiratory system to oscillate at a given frequency and 2) the degree to which the relation between oscillations in ventilation and oscillations in arterial blood gas values is linear. The underlying hypothesis is that periodic breathing results from negative feedback regulation of arterial O2 and CO2 pressure through the chemoreflexes. The double-loop gain describes the gain in the negative feedback loop under the assumption that accidental changes occur in both ventilation and arterial blood gas pressures. A simple version of the double-loop gain is derived from nasal pressure changes and arterial O2 saturation . From all-night recordings, the *double-loop index* (DLI) can be derived, which is determined by the time during which the double-loop gain exceeds a given threshold.
Currently, the presence of sleep-apnea and its clinical significance are determined by the apnea-hypopnea index (AHI), using in-hospital sleep recording. With a growing number of referrals, waiting lists for sleep registration are emerging. Screening for SAS using home-measurement of nasal pressure and SaO2 seems to be a good alternative. We hypothesize that the DLI derived from these signals gives a better reflection of the pathophysiology of the disease than the AHI, which does not take into account the inherent

periodicity of the breathing pattern. As a result, we expect that the DLI improves the distinction between healthy and diseased subjects in comparison to the simple counting of apneas and hypopneas.This is reflected by a higher area under the ROC curve, which describes the sensitivity and specificity of the test.

Study objective

Primary objectives:

1. To determine the DLI threshold with optimal sensitivity and specificity. The DLI threshold is the DLI value above which the test is considered positive (and below which the test is considered negative). The optimal DLI threshold will be taken as the value that gives the highest area under the ROC curve.

2. To test the hypothesis that the sensitivity and specificity of the screening are higher when the DLI is used instead of the AHI (both derived from the same home measurements of nasal pressure and SaO2).

Secundary objective:

1. To assess the repeatability of the DLI using home and in-hospital recordings of nasal pressure and SaO2.

Study design

observational study without intervention

Study burden and risks

In addition to standard in hospital sleep registration patients are asked to perform a one night registration of nasal pressure and O2 saturation at home. The have to collect the equipment and return it the next day. No known risks are associated with this procedure. In the future this screening method may reduce the number of hospital admissions for sleep registration.

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

possible sleep apnea syndrome
> 18 yr
outpatient
able and willing to use the necessary equipment to measure nasal pressure and O2 saturation at home

Exclusion criteria

hospitalized patients
< 18 yr
not able to use the necessary equipment

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	05-12-2008
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	NL21436.094.08