A prospective observational cohort study to investigate predictors for comorbid insomnia in obstructive sleep apnea (COMISA)

Published: 19-01-2021
Last updated: 08-04-2024

To identify characteristics of comorbid insomnia in patients with OSA as a factor for predicting CPAP compliance. To answer this, the aim can be divided into three parts with corresponding research questions. Part 1: Identification of COMISA…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON49679

Source
ToetsingOnline

Brief title
Prediction of insomnia in sleep apnea

Condition

- Other condition

Synonym
OSA and insomnia

Health condition

slaapstoornissen

Research involving

Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: HTSM/STW,Amphia Ziekenhuis;Philips Electronics;Eindhoven Engine,Philips

Intervention

Keyword: comisa, CPAP, insomnia, sleep apnea

Outcome measures

Primary outcome

Demographic parameters: age, gender, BMI

Polysomnography derived parameters:

* macrostructural sleep parameters

* number of apnea/hypopnea events per hour of sleep: apena-hypopnea index (AHI)

* oxygen saturation

Sleep diary derived parameters:

* subjective macrostructural parameters

* night-to-night variability of sleep parameters

* estimators of misperception and other comparisons between objective and

subjective sleep data

Sleep disorders diagnosis: OSA, COMISA, insomnia, other

CPAP compliance (read out from CPAP device):

* number of hours the CPAP device has been used

* AHI

PPG and accelerometry derived parameters:

* macrostructural sleep parameters

* night-to-night variability of sleep parameters

Questionnaires:

* Epworth Sleepiness Scale (ESS)

* Insomnia Severity Index (ISI)

* Hospital Anxiety and Depression scale (HADS)

* Pittsburgh Sleep Quality Index (PSQI)

* Pre-Sleep Arousal Scale (PSAS)

Secondary outcome

not applicable

Study description

Background summary

Currently, Continuous Positive Airway Pressure (CPAP) therapy is the treatment of choice for Obstructive Sleep Apnea (OSA), but a significant percentage of patients is or becomes non-compliant. It is hypothesized that insomnia may play a crucial role in CPAP adherence as OSA and insomnia frequently co-exist. This condition is referred to as comorbid insomnia and OSA: or called COMISA. However, it remains challenging to predict or diagnose COMISA, since insomnia complaints can appear minor compared to the OSA complaints, and insomnia can be masked by sleep fragmentation caused by obstructive events. Additionally, somnological expertise to diagnose insomnia in the presence of external sleep disruptors may be lacking. The diagnosis of insomnia relies on subjective assessments of sleep quality and complaints, while the diagnosis of OSA is based on a single-night polysomnography (PSG) measurement. However, long-term sleep measurements could play a pivotal role in obtaining more insight in a patient*s sleep pattern.
This prospective study will focus on phenotyping patients suspected of OSA, using PSG measurements and modern unobtrusive home-assessment techniques to evaluate both objective and subjective sleep.

Study objective

To identify characteristics of comorbid insomnia in patients with OSA as a factor for predicting CPAP compliance.

To answer this, the aim can be divided into three parts with corresponding research questions.

Part 1: Identification of COMISA subtypes
Question 1a. Is it possible to recognize and identify COMISA subtypes?

Part 2: Prediction of comorbid insomnia in patients suspected for OSA.
Question 2a. Which parameters predict an (*Overt*) COMISA diagnosis in patients suspected for OSA before treatment?
Question 2b. Which parameters predict a change from an initial pre-treatment diagnosis OSA towards a final diagnosis of (*Masked* or *Induced*) COMISA after treatment with CPAP?

Part 3: Prediction of CPAP compliance in patients (initially) diagnosed with OSA or COMISA.
Question 3a. Which parameters predict whether a patient will be compliant to CPAP or not?

Study design

Prospective observational cohort study, in patients referred for suspected OSA to the Amphia sleep center, a large second-line facility for sleep disorders. For this population, normal routine clinical investigation includes ambulatory PSG and assessment of daytime sleepiness using the Epworth Sleepiness Scale (ESS) questionnaire. The treating physician will make a diagnosis according to this clinical information and a clinical interview.
Participants of the study will receive standard clinical care according to the procedure above.

As part of the study, three types of measurements will be added.
1. Wrist-worn photoplethysmography (PPG) measurements will be performed at home during the night, for two weeks. The aim of this measurement is to obtain objective heart rate variability (HRV) measurements on which sleep staging can be performed, yielding insight in long-term sleep patterns and night-to-night variability.
2. An electronic version of a sleep diary will be kept for two weeks (during the same weeks as the PPG measurements). Electronic versions enable us to derive sleep parameters automatically and to compare these subjective results with the objective results from PPG measurements.
3. Digital questionnaires will be completed to obtain subjective information to assess day- and nighttime complaints, anxiety and depression symptoms, sleep quality and nocturnal arousals..

If patients are diagnosed with OSA or COMISA ánd receive CPAP-therapy as part of their treatment, both wrist-worn PPG measurements and sleep diary will be repeated for two weeks after ten weeks of treatment. In addition, the Insomnia

Severity Index (ISI) questionnaire and and the Epworth Sleepiness Scale (ESS) questionnaire will be completed for a second time to assess day- and nighttime components of insomnia and daytime sleepiness after treatment.

Study burden and risks

There are no direct clinical benefits for the subjects, but it is expected that the measurements and analysis will reveal characteristics of comorbid insomnia in OSA to predict CPAP compliance. This may contribute to enhance methods for diagnosis and appropriate treatment in this highly prevalent comorbid disorder. The burden for participants is limited, since an unobtrusive wearable, a simple sleep diary and questionnaires will be used for the study. Further, participants will undergo routine clinical investigation.

Contacts

Public
Amphia Ziekenhuis

Molengracht 21
Breda 4818CK
NL
Scientific
Amphia Ziekenhuis

Molengracht 21
Breda 4818CK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Referred to Sleep Center Amphia for suspected OSA
Planned for polysomnography
Be in possession of a computer with internet

Exclusion criteria

Pregnancy
Autonomic dysfunction (e.g. Parkinson's disease)
Persistent heart rhythm disorders (e.g. Atrium Fibrillation)
Use of alpha- and/or beta-blockers

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2021
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	19-01-2021
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO Date:	27-12-2021
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL73178.015.20
Other	trialregister.nl NL8943