Validation of a screening algorithm for exluding sleep apnea.

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We hypothesize that sleep apnea screening, using a combination of an online questionnaire and high resolution overnight oximetry, can safely be applied to exclude sleep apnea with high sensitivity (≥97%) and acceptable specificity (≥60%) in patients...

Ethical review	Positive opinion
Status	Recruiting
Health condition type	Respiratory tract signs and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON25354

Source
Nationaal Trial Register

Brief title
OSAsenseS18 trial

Condition

- Respiratory tract signs and symptoms

Synonym
Apneas, fatigue, metabolic syndrome, hypertension, atrial fibrillation

Health condition

Sleep apnea is a sleep-related breathing disorder in which repetitive pauses in breathing, periods of shallow breathing, or collapse of the upper airway during sleep results in poor ventilation and sleep disruption.

Research involving
Human

Sponsors and support

Primary sponsor: Medical Spectrum Twente, Enschede, The Netherlands.
Source(s) of monetary or material Support: Medical Spectrum Twente, Enschede, The Netherlands.

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

The primary study endpoints are the sensitivity and negative predictive value of the screening algorithm to detect sleep apnea.

Secondary outcome

Secondary endpoints are the specificity and positive predictive value of the screening algorithm as well as quantification of the occurrence of alternative sleep disorders in patients in who sleep apnea was initially suspected.

Study description

Background summary

This study is a prospective multicenter trial aimed at external validation of an optimized screening algorithm (consisting of an online questionnaire combined with high-resolution overnight oximetry) for the exclusion of sleep apnea in patients presenting with symptoms possibly due to sleep apnea. Polysomnography will be applied as a gold standard to confirm or exclude the final diagnosis of sleep apnea. The primary study endpoints are the sensitivity and negative predictive value of the screening algorithm to detect sleep apnea. Secondary endpoints are the specificity and positive predictive value of the screening algorithm as well as quantification of the occurrence of alternative sleep disorders in patients in who sleep apnea was initially suspected.

Study objective

We hypothesize that sleep apnea screening, using a combination of an online questionnaire and high resolution overnight oximetry, can safely be applied to exclude sleep apnea with high sensitivity (≥97%) and acceptable specificity (≥60%) in patients in who sleep apnea was

initially suspected based on symptoms.

Study design

Patients will fill out an online questionnaire prior to the polysomnography. In addition, patients will wear an OSAsenseS18 device (oximeter) on the contralateral wrist on the night of the polysomnography.

Contacts

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Eligibility criteria

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

Inclusion criteria

Patients aged 18 years or older who present with signs or symptoms possibly due to sleep apnea and who are planned to undergo polysomnography for final diagnosis.

Exclusion criteria

Patients who are legally incapable or in who only a polygraphy (i.e. no polysomnography) is performed are excluded from the study.

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Screening

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2022
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medical device
Brand name:	OSAsenseS18 wearable

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-06-2019
Application type:	First submission

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
NTR-new	NL7797
Other	METC MST : METC19133

Study results