DiagnOSAS as a screeningstool for obstructive sleep apnea syndrome in the primary care setting

Published: 19-01-2016
Last updated: 19-04-2024

By offering a screeningstool for OSAS in the first line (general practitioners), it is expected that diagnosing OSAS becomes easier, faster, cheaper, more efficient, patientfriendly, and is also accessible to a wider audience.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Observational non invasive

Summary

ID

NL-OMON46246

Source
ToetsingOnline

Brief title
DiagnOSAS as a screeningstool for OSAS in the primary care setting

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
Obstructive (sleep) apnea syndrome, oxygen shortage due to a mechanical airway obstruction whilst sleeping

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: MIRA voucher subsidie (Universiteit

Twente/MENZIS) t.w.v. 50.000 euro (26/11/2015 toegekend);zie ook: https://www.utwente.nl/nieuws/!/2015/11/385155/pioneers-in-health-care-innovatievouchers-uitgereikt

Intervention

Keyword: Diagnostic tool, Obstructive sleep apnea syndrome, Primary care, Pulsoximetry

Outcome measures

Primary outcome

To assess the diagnostic value of DiagnOSAS as diagnostic marker for OSAS in

the first line in terms of positive predictive value and sensitivity.

Polygraphy is hereby considered the gold standard.

Secondary outcome

i) Negative predictive value and specificity of pulse-oximetry as diagnostic

marker for OSAS in the first line.

ii) Negative predicitive value, positive predictive value, sensitivity, and

specificity of the Philips questionnaire as diagnostic marker for OSAS.

iii) Usability of DiagnOSAS for patients.

iv) Realized cost savings when using DiagnOSAS with respect to the gold

standard.

Study description

Background summary

DiagnOSAS (Diagnosis - Obstructive Sleep Apnea Syndrome) focuses on patients with unexplained daytime symptoms of tiredness and sleepiness with or without observed breathing stops and suspected by the general practisoner of obstructive sleep apnea syndrome (OSAS).

In obstructive sleep apnea syndrome, patients have accompanying symptoms and

also a positive sleep study A sleep study is considerd positive if the apneu/hypopnea index is at least five, indicating that more than five breathing events occur per hour of sleep. During these breathing events (apneas or hyopneas), the blood oxygen content decreases to a point that the body emmits a reaction to wake up in order to start breathing again. The patient is often not aware of this.

This 'wake up reaction' disturbs the sleep pattern which prohibits the patient to rest fully during the night. As a consequence, patients are sleepy during the day, function worse in their work and have an increased risk of serious accidents at work and / or in traffic. In recent years, it has also become known that OSAS is associated with a strongly increased risk of cardiovascular and vascular disorders, including hypertension, arrhythmias and the development of a heart attack or stroke. In addition, there is an increased risk of developing diabetes, malignancies and dementia. Timely diagnosis and treatment of OSAS is of vital importance to prevent both short and long term health damage.

Annually, over 40,000 patients are referred by their GP to a sleep center with suspected OSAS. Here, they are evaluated by a (team of) medical specialist(s) and undergo numerous tests of which the most important is the poly(somno)graphy. During such a test, several sensors are attached to the patient in order to measure various variables during the night. The polygraphy is stressful for the patient, time-consuming and also associated with high costs. Furthermore, the waiting lists to undergo a polygraphy is growing and therefore the (suspected) patients suffer from their complaints longer than necessary.

Recent figures show that only 50% of patients referred to a sleep center actually suffers from OSAS. On the other hand, approximately 80% of patients who suffer from OSAS did not initially present with fatique symptoms at their GP visit. It is estimated that several hundred thousand Dutch people are not aware that they have Obstructive Sleep Apnea but are exposed to the harmful (health) effects on a daily basis.

A better pre-selection of patients is needed in order to refer patients with a very high suspicion of have OSAS and at the same time not referring patients with a very low probablity of having OSAS. An accessible, simple, reliable and inexpensive screening tool is required for this. With DiagnOSAS we hope to meet this need.

Previous studies suggest that OSAS can also be established with the aid of a nocturnal saturation measurement (pulse-oximetry). The reliability of nocturnal pulse-oximetry would be similar to that of polygraphy. Moreover, a recent study among more than 4,000 Philips employees, suggests that the absence of OSAS can be identified with reasonable reliabilty using a simple questionnaire.

DiagnOSAS combines the use of an (online) questionnaire with data obtained by means of night-time pulse-oximetry. In the present study, the diagnostic parameters of DiagnOSAS for determining OSAS will be examined and compared with polygraphy as the gold standard. The ultimate aim is to develop DiagnOSAS into a reliable screening tool for OSAS for the general practice.

By offering a screeningstool for OSAS in the first line (general practitioners), it is expected that diagnosing OSAS becomes easier, faster, cheaper, more efficient, patientfriendly, and is also accessible to a wider audience.

Study objective

By offering a screeningstool for OSAS in the first line (general practitioners), it is expected that diagnosing OSAS becomes easier, faster, cheaper, more efficient, patientfriendly, and is also accessible to a wider audience.

Study design

The current study is an observational study on the diagnostic value of DiagnOSAS for identifying obstructive sleep apnea syndrome in 150 subjects (> 18 years) with suspected obstructive sleep apnea syndrome (OSAS) who are referred by their GP to a sleep center for further diagnostics (polygraphy). The subjects will complete a brief online questionnaire (25 items). In addition, the oxygen level in the blood is noninvasively recorded by a nocturnal pulse-oximetry in the comfort of their own home. After this night, the subjects undergo polygraphy, which is currently the standard diagnostics for obstructive sleep apnea syndrome and also acts as a gold standard.

Study burden and risks

Burden and risk to study participants was held to a minimum. Burden for the patient for the DiagnOSAS study implies that they have to spend a night at home with a (comfortable) pulse-oximeter. Wearing a "watch" can be experienced as stressful by the patient, but carries no expected adverse events. In addition, the completion of a questionnaire (25 items) is required. The questionnaire is soley a burden for time. There are no questions included which may cause ethical concerns. The questionnaire has been used in previous research. Finally, the patient will have to go to their GP twice more than otherwise necessary for collection / delivery of the pulse oximeter. There are no expected serious adverse events. There are no further expected risks to the investigation.

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

- Age: >18 years
- Patients referred to a specialised center by general practitioners due to the suspicion of having sleep apnea syndrome

Exclusion criteria

- Bodily deformaties making the wearing of a finger pulse oximeter impossible
- Incompetent patients

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):	10-03-2016
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	19-01-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	28-04-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	14-07-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	18-11-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Approved WMO

Date:	12-01-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	17-05-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	22-06-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	03-08-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NL54752.044.15
Other	NRT nummer volgt (binnen 4 weken)

Study results

Date completed:	23-12-2017

Actual enrolment:	164