Ontwikkeling en validatie van een screeningsinstrument voor Obstructief Slaap Apneu Syndroom.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25523

Source
Nationaal Trial Register

Brief title
Developing a tool for screening OSAS

Health condition

Obstructive sleep Apnea

Sponsors and support

Primary sponsor: Philips NV
Amstelplein 2
1096 BC.
Amsterdam
Source(s) of monetary or material Support: Philips NV
Amstelplein 2
1096 BC.
Amsterdam

Intervention

Outcome measures

Primary outcome

Find the best 2 or 3 step strategy for screening of OSAS in a Dutch employee population to optimize a large scale screening program. Home PSG with the ALICE PDX, combined with answers on sleepiness will be used for confirmation. This includes the following:

1. Which questionnaire, or set of questions has the highest accuracy in terms of sensitivity, specificity and positive and negative predictive value;

2. Define the low and high cut-off values of the used questionnaires for negative and positive test results;

3. Are limited IV home sleep studies in this population feasible;

4. What is the accuracy of the complete strategy.

Secondary outcome

1. Calculate the costs of the strategy;

2. Estimate the prevalence of OSAS in this population;

3. Estimate the prevalence of Excessive Daytime Sleepiness in this population.

Study description

Background summary

Rationale:

The Obstructive Sleep Apnea Syndrome (OSAS) is a disorder that is characterized by repetitive episodic partial or complete collapse of the pharyngeal airway. These nocturnal events interfere with normal restorative sleep and are responsible for the daytime symptoms like excessive daytime sleepiness, poor concentration and fatigue. OSAS is associated with increased cardio vascular and cerebrovascular morbidity and mortality. Philips NV Netherlands is planning to screen a large part of their Dutch work force (approximately 16.000 employees) for OSAS. Because of these large numbers a simple, but sensitive and specific screening strategy needs to be developed and tested. The proposed study will investigate and validate in a population of approximately 300 healthy workers from Philips NV a set of diagnostic questionnaires, supplemented with airflow registration with the RU sleeping device. The gold standard will be the combined result from Polysomnography (PSG), performed at home, and answers to questions on sleepiness from questionnaires.

Primary Objective(s):

Find the best 2 or 3 step strategy for screening of OSAS in a Dutch employee population to optimize a large scale screening program. Home PSG, combined with answers on sleepiness, will be used for confirmation. This includes the following:

1. Which questionnaire, or set of questions has the highest accuracy in terms of sensitivity, specificity and positive and negative predictive value;

2. Define the low and high cut-off values of the used questionnaires for negative and positive test results;

3. Are limited IV home sleep studies in this population feasible;

4. What is the accuracy of the complete strategy.

Secondary Objective(s):

1. Calculate the costs of the strategy;

2. Estimate the prevalence of OSAS in this population;

3. Estimate the prevalence of Excessive Daytime Sleepiness in this population.

Study design:

The study will be designed as a diagnostic study.

Study population:

Healthy workers from Philips NV.

Main study parameters/endpoints:

The main study parameters are sensitivity, specificity, positive and negative predictive values, and ROC Area Under the Curve. These will be calculated for each of the questionnaires and for all individual questions separately (step 1), and home screening by airflow registration with the RU sleeping device (step 2). Home PSG, combined with answers on sleepiness, is the gold standard in this study.

Study objective

N/A

Study design

This is a diagnostic study with measurements within two/three weeks.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Subjects have to have a fixed employment contract with Philips Nederland;

2. Subjects have to work at either Philips Nederland gebouw VB, Eindhoven or Philips Healthcare, Best.

Exclusion criteria

Temporary workers.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2011
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-01-2011
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	NL2557
NTR-old	NTR2675
Other	METC : P10-49
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A