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

Gepubliceerd: 03-01-2011 Laatst bijgewerkt: 18-08-2022

N/A

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25523

Bron
Nationaal Trial Register

Verkorte titel
Developing a tool for screening OSAS

Aandoening

Obstructive sleep Apnea

Ondersteuning

Primaire sponsor: Philips NV
Amstelplein 2
1096 BC.
Amsterdam
Overige ondersteuning: Philips NV
Amstelplein 2
1096 BC.
Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

N/A

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Temporary workers.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-01-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2557
NTR-old	NTR2675
Ander register	METC : P10-49
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A