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Primary hypothesis: Position therapy reduces sleep time in supine posture using the Sleep Position Trainer (SPT) in equal amount as the position band (PB) in patients with mild and moderate positional OSAS. Secondary hypothesis: The Sleep...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

Bron

NTR

Verkorte titel

POST

Aandoening

Positional Obstructive Sleep Apnea Syndrome, OSAS

Ondersteuning

Primaire sponsor :	Medisch Spectrum Twente
Overige ondersteuning :	Medisch Spectrum Twente

Onderzoeksproduct en/of interventie

Geen registraties gevonden.

Uitkomstmaten

Primaire uitkomstmaten

Sleeping time in supine posture as percentage of total sleep time (%STS) and compliance.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

This study tries to answer the call for the search of a comfortable and ergonomic positional therapy, which increases compliance for positional therapy in posture dependent OSAS patients.

Objective:

To assess equivalence in reducing sleep time in supine posture between positional therapy using the position training device and the sleep position band in patients with mild and moderate positional OSAS.

Design:

This study will be conducted according to an open randomized controlled trial design at Medisch Spectrum Twente, Enschede.

Population:

The subjects for the study will be recruited from the department of pulmonary medicine at Medisch Spectrum Twente in Enschede and Oldenzaal, the Netherlands. Subjects will be males and females with diagnosis of symptomatic mild or moderate OSAS ($5 < AHI < 30$) and the diagnosis positional OSAS ($2*AHI_{nonsupine} \leq AHI_{supine}$ & $AHI_{nonsupine} < 5$).

Intervention:

Subjects will sleep every night with the position training device during a 1 month period. The small device is placed in an elastic band stretched around the subject's lower chest. During sleep the device registers the sleep position of the subject and it will vibrate when the subject lays in supine posture. The positional therapy that is used as control consists of the subject getting a sleep position band. Whenever a patient rolls into supine posture during sleep, he feels the pressure of the ball and is likely to change his posture.

Doel van het onderzoek

Primary hypothesis: Position therapy reduces sleep time in supine posture using the Sleep Position Trainer (SPT) in equal amount as the position band (PB) in patients with mild and moderate positional OSAS.

Secondary hypothesis: The Sleep Position Trainer (SPT) increases patient's compliance compared to the position band (PB).

Onderzoeksopzet

Subjects will sleep with the device during a 1 month period. Measurements will take place before and right after the intervention.

Onderzoeksproduct en/of interventie

Subjects will sleep every night with the position training device during a 1 month period. The small device is placed in an elastic band stretched around the subject's lower chest. During sleep the device registers the sleep position of the subject and it will vibrate when the subject lays in supine posture.

The positional therapy that is used as control consists of the subject getting a sleep position band. Whenever a patient rolls into supine posture during sleep, he feels the pressure of the obstruction and is likely to change his posture.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 18 years or older;

2. Ability to understand, read and write Dutch;

3. Ability to follow up;

4. Diagnosis of symptomatic mild or moderate OSAS (5 < AHI < 30);

5. Diagnosis positional OSAS (2*AHInonsupine ≤ AHIsupine);

6. AHInonsupine < 5.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Central sleep apnea syndrome / Cheyne-Stokes respiration;

2. Signs of severe nasal obstruction;

3. Major facial or pharyngeal anatomic abnormalities likely to require surgery;

4. Night or rotating shift work;

5. Severe chronic heart failure;

6. Known history of a known cause of daytime sleepiness and severe sleep disruption (e.g. insomnia, PLMS, narcolepsy);

7. Seizure disorder;

8. Known medical history of mental retardation, memory disorders or psychiatric disorders;

9. The inability to provide informed consent.

Onderzoeksopzet

Opzet

Type :	Interventie onderzoek
Onderzoeksmodel :	Parallel
Toewijzing :	Gerandomiseerd
Blindering :	Open / niet geblindeerd
Controle :	Geneesmiddel

Deelname

Nederland

Status :	Werving nog niet gestart
(Verwachte) startdatum :	14-02-2011
Aantal proefpersonen :	60
Type :	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum :	03-02-2011
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	NL2604
NTR-old	NTR2732
CCMO	NL34934.044.10 / P10-47;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A