POST study.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21942

Source
NTR

Brief title
POST

Health condition

Positional Obstructive Sleep Apnea Syndrome, OSAS

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Medisch Spectrum Twente

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Mean SaO2;

2. Lowest SaO2;

3. Apneu Hypopneu Index (AHI);

4. Apneu Hypopneu Index in supine posture (AHIs);

5. Apneu Hypopneu Index in nonsupine posture (AHIns);

6. Total Sleep Time;

7. Total Sleep Time with SaO2 < 90%;

8. Symptom reduction;

9. Therapy preference.

Study description

Background summary

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*AHInonsupine ≤ AHIsupine & AHInonsupine < 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.

Study objective

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).

Study design

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

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 obstruction and is likely to change his posture.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-02-2011
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-02-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36753
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2604
NTR-old	NTR2732
CCMO	NL34934.044.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36753

Study results

Summary results
N/A