Use of the Z-cushion in patients with positional Obstructive Sleep Apnea Syndrome.

No registrations found.

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

Summary

ID

NL-OMON25515

Source
NTR

Brief title
Z-cushion in OSAS

Health condition

Obstructive Sleep Apnea Syndrome
Obstructief Slaap Apneu Syndroom

Sponsors and support

Primary sponsor: Gelre ziekenhuizen
Zutphen
Source(s) of monetary or material Support: Department of Pulmonary Medicine
Gelre ziekenhuizen
Zutphen

Intervention

Outcome measures

Primary outcome

Assessing the efficacy in Apnea-Hypopnea Index (AHI) reduction using the Z-cushion compared to delay of treatment in patients with mild and moderate positional OSAS. AHI will be assessed by PSG.

Secondary outcome

Assessing the efficacy with regard to:

1. Sleepiness;

2. Reducing the sleep time in supine posture;

3. Reducing the number of O2 saturation dips;

using the Z-cushion compared to delay of treatment in patients with mild and moderate positional OSAS.

Sleepiness will be assessed by the Epworth Sleepiness Scale. (M. W. Johns, 1991; 1994).

Sleep time in supine posture and O2 saturation dips will be assessed by PSG.

Study description

Background summary

“Use of the Z-cushion in patients with positional Obstructive Sleep Apnea Syndrome: A randomized controlled trial”.

Rationale:

The diagnosis of OSAS is based on the presence of symptoms (e.g. snoring, sleepiness, fatigue and inattention) and the apnea-hypopnea index (AHI). The syndrome can be divided in positional and non-positional OSAS. Positional dependent OSAS patients show an increase in sleep-related breathing abnormalities when lying in the supine sleeping position compared to the lateral sleeping position. Positional therapy is recently gaining interest of pulmonologists for the treatment of mild OSAS where 49.5 percent of the patients are position dependent. Positional therapy seems to be equivalent to the use of CPAP in the ability to normalize the AHI in this group of patient with mild OSAS. The positional therapy consists of the patient stitching a pocket with a tennis ball inside onto the back of his pyjama, also called the tennis ball technique (TBT). However this positional therapy has a low patient

compliance, because many patients experience this treatment as too uncomfortable to carry on with. This study tries to answer the call for the search of a comfortable and ergonomic positional therapy, which increases compliance for this therapy in positional OSAS patients.

Objective:

To assess the efficacy of reducing the sleep time in supine posture with positional therapy using the Z-cushion compared to compared to delay of treatment in patients with mild and moderate positional OSAS.

Study design:

This study will be conducted according to an open randomized controlled trial design at Gelre Hospital in Zutphen.

Study population:

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

Intervention:

Subjects will sleep every night with the Z-cushion 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.

Main study parameters/endpoints:

Assessing the efficacy in AHI reduction using the Z-cushion compared to delay of treatment in patients with mild and moderate positional OSAS. AHI will be assessed by PSG.

Study objective

To assess the efficacy of reducing the sleep time in supine posture with positional therapy

using the Z-cushion compared to compared to delay of treatment in patients with mild and moderate positional OSAS.

Study design

Baseline and 1 month.

Intervention

Subjects who participate in this study will sleep one month with either the Z-cushion (NEG 0608) or will receive no treatment for the first month.

Contacts

Public
Gelre ziekenhuizen
Department of Pulmonary Medicine
Den Elterweg 77
E. Lammers
Zutphen 7207 AE
The Netherlands
+31 (0)57 5592924
Scientific
Gelre ziekenhuizen
Department of Pulmonary Medicine
Den Elterweg 77
E. Lammers
Zutphen 7207 AE
The Netherlands
+31 (0)57 5592924

Eligibility criteria

Inclusion criteria

1. 18 years or older;

2. Ability to understand and read Dutch;

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

4. Diagnosis positional OSAS (2*AHInonsupine ≤ AHIsupine).

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2011
Enrollment:	44
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-03-2011
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	NL2696
NTR-old	NTR2826
Other	METC Twente : P11-18
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A