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

Gepubliceerd: 28-03-2011 Laatst bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON25515

Bron
NTR

Verkorte titel
Z-cushion in OSAS

Aandoening

Obstructive Sleep Apnea Syndrome
Obstructief Slaap Apneu Syndroom

Ondersteuning

Primaire sponsor: Gelre ziekenhuizen
Zutphen
Overige ondersteuning: Department of Pulmonary Medicine
Gelre ziekenhuizen
Zutphen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

“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*AHInonsupine ≤ AHIsupine).

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Baseline and 1 month.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2011
Aantal proefpersonen:	44
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-03-2011
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	NL2696
NTR-old	NTR2826
Ander register	METC Twente : P11-18
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A