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

Published: 05-07-2011
Last updated: 27-04-2024

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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON36124

Source
ToetsingOnline

Brief title
Z-cushion

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
Disturbed breathing, Obstructive Sleep Apnea

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Obstructive, Randomised Controlled Trial, Sleep Apnea

Outcome measures

Primary outcome

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.

Secondary outcome

Assessing the efficacy with regard to

• sleepiness

• reducing the sleep time in supine posture

• 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

Obstructive Sleep Apnea Syndrome (OSAS) is an affliction, characterised by repeated episodes of complete or partial collapse of the upper airways. The nocturnal episodes interfere with normal, restful sleep and are responsible for symptoms such as extreme tiredness, poor concentration, and fatigue. OSAS is also associated with an increased risk of cardiovascular and cerebrovascular morbidity and mortality. 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.

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

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

Intervention

Subjects will sleep every night with the Z-cushion during a 1 month period.

Study burden and risks

There is no risk associated with the study. The benefit will be in reducing sleepiness. OSAS treatment can only be done in OSAS patients. The burden is limited to one extra polysomnograpy in a sleep centre.

Contacts

Public
Gelre Ziekenhuizen

Den Elterweg 77
7207 AE Zutphen

NL
Scientific
Gelre Ziekenhuizen

Den Elterweg 77
7207 AE Zutphen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years or older
Ability to understand and read Dutch
Diagnosis of symptomatic mild or moderate OSAS (5 < AHI < 30)
Diagnosis positional OSAS (2*AHInonsupine <= AHIsupine)

Exclusion criteria

Central sleep apnea syndrome / Cheyne-Stokes respiration
Signs of severe nasal obstruction
Major facial or pharyngeal anatomic abnormalities likely to require surgery
Night or rotating shift work
Severe chronic heart failure
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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-08-2011
Enrollment:	44
Type:	Actual

Medical products/devices used

Generic name:	Z-Pillow (NEG 0608)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	05-07-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
CCMO	NL35682.044.11