Sleep position trainer versus MRA: a randomised controlled cross-over clinical trial

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Primary Objective: Evaluation of effectiveness (AHI using PSG) of SPT when compared to MRA in patients with mild to moderate positional dependent obstructive sleep apnea (POSA) in a non-inferiority setting for a short (3 months) and longterm (12…

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

Summary

ID

NL-OMON46521

Source
ToetsingOnline

Brief title
SLEMRA

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
positional / supine dependent, sleep apneu / shallow breathing

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: De slaappositietrainers worden door NightBalance beschikbaar gesteld en de chip in de MRA wordt door Somnomed beschikbaar

gesteld,NightBalance ,Somnomed (Nederland)

Intervention

Keyword: OSAS, position, SPT, trainer

Outcome measures

Primary outcome

- Apneu-hypopneu index (AHI using PSG)

Secondary outcome

- Oxygen desaturation index (ODI in PSG)

- AHI in supine position (PSG)

- Eppworth sleepiness scale (ESS questionnaire)

- Compliance (Somnomed dentitrac and Nightbalance) after 3 and 9 months of treatment

- Mean disease alleviation (MDA) as the product of the adjusted compliance with the therapeutic efficacy divided by 100 (%)

- Total sleep time (TST in PSG)

- Sleepposition, percentage of sleep in supine-position (PSG)

- FOSQ-10

- SF-36

- Total costs

- MFIQ (Mandibular function impairment questionnaire)

- Sleepposition (including % in supine position, PSG, nightbalance, DentiTrac)

- Patient satisfaction (questionaires, numerical rating scale (NRS) / visual analoge scale (VAS), including sleepiness and fatigue)

- Snoring (patient / bedpartner reported NRS / VAS 0-10)

- Patient anamnesis / diary (usage, hinder, alcoholusage)

- Partner satisfaction (snoring, movement, disturbance of sleep due to therapy)

- Therapy preference (questionnaire)

- Sleepstages (PSG)

- Sleepefficiency (PSG)

- Adverse events

Study description

Background summary

Obstructive sleep apnea syndrome (OSA) is the most common sleep-related breathing disorder. Mandibular reposition apparatus (MRA) is the treatment of choice for mild to moderate OSA, with adherence of 81%. 23-71.4 % of patients with OSA have a position dependent OSA (POSA). There are several different definitions of POSA. The one that is used most often and which is most honest, and posed by Mador is that in which the apnea-hypopnoea index (AHI) in non-supine sleeping position is less than 5 /h instead of the also used definition as used by Marklund et al[2, 3]. There have been several treatment options in the past to adjust the sleep position, however without consistent success, and mostly because of lack of compliance. Recently several sleep-position trainers (SPT) have been developed with compact sensors with actuators that register sleep position accurately and which stimulate the patient to alter their sleep position using vibration. In POSA a SPT might be as effective as MRA and the potential treatable group can be larger because 25 % of patients has a contra-indication for MRA because of (peri)dental disorders.

Study objective

Primary Objective: Evaluation of effectiveness (AHI using PSG) of SPT when compared to MRA in patients with mild to moderate positional dependent obstructive sleep apnea (POSA) in a non-inferiority setting for a short (3 months) and longterm (12 months) evaluation period.

Secondary Objective(s): ODI using PSG, ESS, FOSQ-10, compliance short-term (3 months) and long-term (9 months in case of preference) using sensor (Somnomed dentitrac / nightbalance), adverse events, therapy responding, Mean disease alleviation (MDA), total sleep time (TST), sleepposition, total costs and

therapy preference.

Study design

A randomized controlled cross-over clinical trial. It*s a mono-center study in the Center of Sleep Medicine Amphia Hospital Breda/Oosterhout. Patients assessed and diagnosed by poly(somno)graphy of having mild to moderate POSA (AHI 6-29/hour). The first group will be treated initially with MRA for a period of 3 months re-assessed with a PSG and questionnaires for primary outcome measurement and consecutively using SPT during 3 months and again be re-assessed with a PSG and above mentioned questionnaires. The other group will be treated initially with a SPT during 3 months and subsequently for a period of 3 months with MRA. Follow-up of compliance will be 12 months.

Intervention

Sleep-position trainer (SPT)

Study burden and risks

1. 2 polysomnographies extra when compared to standard care (each 1 night).

2. Answering 6 questionairs at a total of 3 timepoints (estimated 13 minutes for each timepoint):
- ESS at 3 timepoints
- FOSQ at 3 timepoints
- SF36 questionaire at 3 timepoints
- MFIQ at 2 timepoints
- Questionaire SPT at 2 timepoints
- Questionaire MRA at 2 timepoints
- Questionaire patientsatisfaction comparing SPT with MRA at 1 timepoint

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Newly diagnosed OSAS patient (according to Dutch guidelines: AHI > 5/hr & * 2 of the following complaints: faltering breathing during sleep, repeatedly startle awakening during sleep, non-refreshing sleep, daytime fatigue, concentrationloss)
- Apnea hypopnea index 6-29/hour
- Time in supine position 10-90 % during the night, AHI/ non supine < 5/hour.
- AHI supine * 2x AHI any other sleeping position
- ESS > 10
- Age 18-70 years of age
- Follow-up possible
- Ability to read and write

Exclusion criteria

- Central sleep apnea or significant central sleep apnea component
- Unsuitable for MRA
- Concentration disorder due to OSAS potentially leading to dangerous situations
- Reversible / treatable upper airway disease (i.e. enlarged tonsils)
- Expectation of great change on physical status during study-period (for example condition with expected great change in bodyweight, pregnancy, operative treatment especially of the face, OSAS-surgery, bariatric surgery)
- Medication for sleep disorder or related to sleeping disorder.
- Known comorbidity causing fatigue or severe sleep disturbances (insomnia, PLMS, narcolepsy)
- Complains of loud snoring in non-supine position

- Neck, shoulder or back problems
- Patients with a diagnosed anxiety disorder
- Mental disorder/retardation
- Impossibility for informed consent
- Nightshift-profession
- Severe cardiac failure
- Epilepsy
- Simultaneous use of other treatment modalities for OSAS
- History of former treatment for OSAS using MRA, CPAP or SPT
- Combination therapy (weight reduction, ENT-surgery, CPAP)
- Other reasons for a strong need for CPAP-therapy
- Expected other changes in physical well-being cause of comorbidity/other diseases and/or expected weight loss or gain such as pregnancy and bariatric surgery.
- BMI > 35 kg/m2.
- Elevation off headside of the bedside more than 30 degrees or sleeping on more than two pillows

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2020
Enrollment:	54
Type:	Actual

Medical products/devices used

Generic name:	Sleep position trainer
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-03-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL64563.101.18