Vergelijking van slaap positie trainer versus slaapbeugel

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26790

Source
NTR

Brief title
SLEMRA

Health condition

OSA
obstructive sleepapnea

Sponsors and support

Primary sponsor: Amphia ziekenhuis
Source(s) of monetary or material Support: Nightbalance (SPT)
Somnomed
Mainly selffinancing

Intervention

Outcome measures

Primary outcome

AHI (total and supine)

ESS

Secondary outcome

- 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 (%)[17]

- Total sleep time (TST)

- Sleepposition, percentage of sleep in supine-position

- FOSQ-10 questionaire (appendix)

- SF-36 questionaire (appendix)

- MFIQ (Mandibular function impairment questionnaire, appendix)

- Total costs

- Sleepposition (including % in supine position, as acquired by Zorginstituut Nederland)

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

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

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

- Partner satisfaction (snoring, movement, disturbance of sleep due to therapyy, NRS 0-5) (appendix 19, 20)

- Therapy preference

- Sleepstages

- Sleepefficiency

- Adverse events

Study description

Background summary

SPT is expected to perform as wel as MRA in sleepposition dependent OSA. Patients will be

treated sequentially with both therapies in 2 groupes. Group 1 will start with SPT for 3 months and then stop with SPT and start with MRA. The other group start with MRA and finishes with SPT, each for 3 months. After a total of 6 months patients can continue the treatment of choiceif effective and will undergo follow-up for 6 months.

Study objective

SPT is as effective as MRA in sleep-position dependent OSA

Study design

3 months, 6 months, 12 months

Intervention

SPT (sleep position trainer)

MRA (mandibular rteatraction apparatus)

Contacts

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Eligibility criteria

Inclusion criteria

- Newly diagnosed OSA patient (according to Dutch guidelines: AHI > 5/hr & ¡Ý 2 of the following complaints: faltering breathing during sleep, repeatedly startle awakening during sleep, non-refreshing sleep, daytime fatigue, concentrationloss) [11]

- Apnea hypopnea index 6-29/hour

- Time in supine position 10-90 % during the night, AHI/ non supine < 5/hour.

- AHI supine ¡Ý 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 OSA 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, OSA-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 OSA

- History of former treatment for OSA using MRA, CPAP or SPT

- Combination therapy (weight reduction, ENT-surgery, CPAP)

- Other reasons for a strong need for CPAP-therapy

- 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2018
Enrollment:	40
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL6742
NTR-old	NTR6920
CCMO	NL28381.101.18

Study results

Summary results
none