

Vergelijking van slaap positie trainer versus slaapbeugel

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26790

Bron

Nationaal Trial Register

Verkorte titel

SLEMRA

Aandoening

OSA
obstructive sleepapnea

Ondersteuning

Primaire sponsor: Amphia ziekenhuis
Overige ondersteuning: Nightbalance (SPT)
Somnomed
Mainly selffinancing

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

AHI (total and supine)

Toelichting onderzoek

Achtergrond van het onderzoek

SPT is expected to perform as well as MRA in sleep-position dependent OSA. Patients will be treated sequentially with both therapies in 2 groups. 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 choice if effective and will undergo follow-up for 6 months.

Doel van het onderzoek

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

Onderzoeksopzet

3 months, 6 months, 12 months

Onderzoeksproduct en/of interventie

SPT (sleep position trainer)

MRA (mandibular retraction apparatus)

Contactpersonen

Publiek

J. Asin
Breda
The Netherlands
0162-327053

Wetenschappelijk

J. Asin
Breda
The Netherlands
0162-327053

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Newly diagnosed OSA 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) [11]
- Apnea hypopnea index 6-29/hour
- Time in supine position 10-90 % during the night, AHI/ non supine < 5/hour.
- AHI supine $\geq 2 \times$ AHI any other sleeping position
- ESS > 10
- Age 18-70 years of age
- Follow-up possible
- Ability to read and write

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	40

Type:

Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:

Niet van toepassing

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	NL6742
NTR-old	NTR6920
CCMO	NL28381.101.18

Resultaten

Samenvatting resultaten

none