Het verschil tussen een tijdelijke en een op maat gemaakte uitneembare beugel voor de behandeling van slaapapneu

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This study evaluates whether the boil and bite Mandibular Advancement Device (MAD), MyTAP, can be used as a screening tool to predict treatment success with MAD therapy. Besides the boil and bite MyTAP will be compared to a custom MAD, named TAP1,...

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

Samenvatting

ID

NL-OMON28622

Bron
NTR

Verkorte titel
BOBYTE study

Aandoening

Obstructive Sleep Apnea
Mandibular Advancement Device

Ondersteuning

Primaire sponsor: Academic Center Dentistry Amsterdam (ACTA)
Overige ondersteuning: initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• PSG parameters: Baseline AHI, AHI after 12 weeks follow-up with either MyTAP or TAP1 (total AHI, supine AHI, non-supine AHI and ODI
• WristOx parameters: ODI
• DISE outcomes: by using the VOTE classification with and without jaw thrust and MyTAP

Treatment with MyTAP or TAP1 therapy is listed as successful if the AHI reduction either is <5 or showed a 50% reduction from the baseline AHI, with an AHI of at least <10 per hour in a patient without subjective OSA symptoms while using therapy.

Toelichting onderzoek

Achtergrond van het onderzoek

This study evaluates whether the boil and bite MAD, MyTAP, can be used as a screening tool to predict treatment success with MAD therapy. Besides the boil and bite MyTAP will be compared to a custom MAD, named TAP1, on short-term outcomes. The aim of the study is to evaluate DISE outcomes, PSG parameters, WristOx parameters, patient's compliance, satisfaction and improvement in quality of life of a boil and bite MAD and a custom MAD during a follow-up period of 12 weeks.

Doel van het onderzoek

This study evaluates whether the boil and bite Mandibular Advancement Device (MAD), MyTAP, can be used as a screening tool to predict treatment success with MAD therapy. Besides the boil and bite MyTAP will be compared to a custom MAD, named TAP1, on short-term outcomes. The aim of the study is to evaluate Drug Induced Sleep Endoscopy (DISE) outcomes, Polysomnographic parameters, WristOx parameters, patient's compliance, satisfaction and improvement in quality of life of a boil and bite MAD and a custom MAD during a follow-up period of 12 weeks.

Onderzoeksopzet

• DISE outcomes: at baseline

• PSG parameters: at baseline, after 12 weeks follow-up MyTAP, after 12 weeks follow-up TAP1

• WristOx parameters: at baseline, after 12 weeks follow-up MyTAP, after 12 weeks follow-up TAP1

• Questionnaires: at baseline, after 12 weeks follow-up MyTAP, after 12 weeks follow-up TAP1

• Mandibular advancement: after 12 weeks follow-up MyTAP, after 12 weeks follow-up TAP1

• Compliance and treatment satisfaction: after 12 weeks follow-up MyTAP, after 12 weeks follow-up TAP1

• Adverse Events: after 12 weeks follow-up MyTAP, after 12 weeks follow-up TAP1, if necessary

Onderzoeksproduct en/of interventie

54 consecutive OSA patients will be randomized by a cross-over design starting with either the MyTAP or TAP1 therapy. Both interventions are used for a follow-up period of 12 weeks with a washout period of 1 week. After each period of 12 weeks a comprehensive sleep study and questionnaire survey are performed.

Contactpersonen

Publiek

Department of Oral Kinesiology, ACTA, Room 3N-75

JAM Uniken Venema
Gustav Mahlerlaan 3004

Amsterdam
The Netherlands
-

Wetenschappelijk

Department of Oral Kinesiology, ACTA, Room 3N-75

JAM Uniken Venema
Gustav Mahlerlaan 3004

Amsterdam
The Netherlands
-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• >18 years of age

• Diagnosis of OSA confirmed by a PSG (AHI ≥ 5)

• Sufficient understanding of Dutch language in speaking and writing

• Sceduled for a DISE and analysed with a boil and bite MAD

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Medical and psychological criteria:

• Reversible morphological upper airway abnormalities (e.g. enlarged tonsils)

• Clear failure or non-acceptance of previous MAD therapy

• Central Sleep Apnea syndrome (> 50% of central apneas during diagnostic PSG)

• Inability to provided informed consent

Dental criteria:

• (Extensive) periodontal disease or tooth decay (confirmed by Xray).

• Active temporomandibular joint disease (including severe bruxism).

• Restrictions in mouth opening (<25 mm) or advancement of the mandible (<5 mm).

• Partial or complete edentulism (less than 8 teeth in upper or lower jaw).

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2018
Aantal proefpersonen:	58
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48802
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7249
NTR-old	NTR7456

Register	ID
CCMO	NL64738.100.18
OMON	NL-OMON48802

Resultaten