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

No registrations found.

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

Summary

ID

NL-OMON28622

Source
NTR

Brief title
BOBYTE study

Health condition

Obstructive Sleep Apnea
Mandibular Advancement Device

Sponsors and support

Primary sponsor: Academic Center Dentistry Amsterdam (ACTA)
Source(s) of monetary or material Support: initiator = sponsor

Intervention

Outcome measures

Primary outcome

• 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.

Secondary outcome

• Questionnaires: Epworth Sleepiness Scale, Functional Outcomes of Sleep Questionnaire, Short form Survey (RAND36) at baseline, 12 and 25 weeks of follow-up

• Mandibular advancement: percentage of maximal protrusion after 12 weeks of treatment with MyTAP and after 12 weeks of treatment with a custom-made MAD

• Compliance and treatment satisfaction: therapy use in hours/night and nights/week, therapy evaluation

• Adverse Events: possible temporary side effects on short term such as: Hypo or hypersalivation, Sensitive dentition or gums, Sensitive joints or muscles

Study description

Background summary

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.

Study objective

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.

Study design

• 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

Intervention

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.

Contacts

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

JAM Uniken Venema
Gustav Mahlerlaan 3004

Amsterdam
The Netherlands
-
Scientific
Department of Oral Kinesiology, ACTA, Room 3N-75

JAM Uniken Venema
Gustav Mahlerlaan 3004

Amsterdam
The Netherlands
-

Eligibility criteria

Inclusion criteria

• >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

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2018
Enrollment:	58
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 48802
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7249
NTR-old	NTR7456
CCMO	NL64738.100.18
OMON	NL-OMON48802

Study results