The use of a boil and bite Mandibular Advancement Device versus a custom Mandibular Advancement Device in Obstructive Sleep Apnea management

Published: 08-01-2019
Last updated: 19-03-2025

The aim of this study is to evaluate whether the MyTAP can be used as a screening tool to predict treatment success with MAD therapy. This will be evaluated during a 3 month follow-up of the therapy.Secondly, we want to compare the patient...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48802

Source
ToetsingOnline

Brief title
BOBYTE study

Condition

- Other condition
- Upper respiratory tract disorders (excl infections)

Synonym
Obstructive Sleep Apnea, OSA

Health condition

obstructief slaapapneu

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: bedrijven, Airway Management Inc., Dallas, TX, USA,bedrijven;Airway Management Inc.;Dallas;TX;USA

Intervention

Keyword: Mandibular Advancement Device, Obstructive Sleep Apnea Syndrome

Outcome measures

Primary outcome

Polysomnographic parameters (total AHI, supine AHI, non-supine AHI, ODI)

Secondary outcome

OSAsense S18 parameters (ODI)

Outcome of Quality of Life questionnaires;

- Epworth Sleepiness Scale

- Functional Outcome of Sleep Questionnaire

- Short Form Health Survey

Mandibular advancement

Compliance and treatment satisfactionAdverse Events

Study description

Background summary

Mandibular advancement devices (MADs) are commonly used in patients with mild to moderate Obstructive Sleep Apnea (OSA), however they have not a desired effect in all patients.

In order to prevent upper airway obstructions, MADs are designed to advance the

mandible in a forward position. During a drug-induced sleep endoscopy (DISE) a manually jaw thrust is performed in order to predict the possible treatment outcome of MAD therapy. Unfortunately, this manoeuvre might not be representative for the real life effect of a MAD. The use of a simulation bite during DISE has been proposed, but scientific evidence is minimal and new simulation bites are developed. To predict and improve treatment success, a boil and bite simulation bite is a cheap, quick and might be an easy to use system to mimic the effect of a MAD during DISE and is of interest in research settings and habituation. In the METc protocol ABR 66070 the MyTAP is used as a screening tool and compared to the jaw thrust during DISE. The aim of the first study is to compare the effect of manually performed jaw thrust with the effect of the boil and bite MAD, MyTAP, during DISE by using the VOTE classification. 200 patients aged 18 year or older diagnosed with OSA confirmed by a type II polysomnography will be included in this single-centre prospective study. DISE will be assessed three times: with and without manually performed jaw thrust and with the MyTAP in situ.

The MyTAP is a new thermoplastic boil and bite MAD which can also be used as a transitional oral appliance in the treatment of OSA. The devise can be easily fitted within 15 minutes. This allows patients to begin treatment directly and experience the benefits and possible disadvantages of MAD treatment. Besides the MyTAP is an efficient and cost-effective way to find out if MAD treatment is suitable for the patient.

Study objective

The aim of this study is to evaluate whether the MyTAP can be used as a screening tool to predict treatment success with MAD therapy. This will be evaluated during a 3 month follow-up of the therapy.
Secondly, we want to compare the patient compliance and satisfaction of the MyTAP to a custom-made MAD during a follow-up period of 3 months. In addition we want to compare the polysomnographyic outcomes to the OSAsense S18 outcomes to evaluate if the OSAsense S18 is a good treatment evaluater.
Finally PSG outcomes of boil and bite MAD and curstom MAD will be compared with DISE outcomes to evaluate wheather DISE is a good screening tool for MAD therapy and wheather the MyTAP can be used as a screening tool during DISE to predict treatment success with MAD therapy.

Study design

Single-centre prospective cross-over study.

Intervention

58 consecutive OSAS patients will be included in a crossover design and selected for treatment with a custom MAD and a boil and bite MAD. Both

interventions are used for a period of 3 months with a washout of 1 week. After each period of 3 months a PSG, wrist oximetry and secondary questionnaires are performed.

Study burden and risks

Possible risks or side-effects MAD treatment on short term:
- Hypo or hyper salivation
- tooth pain
- sensitive gums
- temporomandibular joint pain or myofacial pain
- small dental changes
- tooth damage

small risk with negligible damage

Contacts

Public
OLVG

Jan Tooropstraat 164
Amsterdam 1061AE
NL
Scientific
OLVG

Jan Tooropstraat 164
Amsterdam 1061AE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

* OSA patient confirmed by a PSG
* 18 years and older
* Sufficient understanding of Dutch language in speaking and writing
* Included in DISE study with METc protocol ARB 66070, NL66070.100.18

Exclusion criteria

Medical and psychological criteria:
* Clear failure or non-acceptance of previous MAD therapy
* Central Sleep Apnea syndrome (> 50% of central apneas)
* Inability to provided informed consent
* Reversible morphological upper airway abnormalities (e.g. enlarged tonsils),
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
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2019
Enrollment:	58

Type:	Actual

Medical products/devices used

Generic name:	Mandibular Advancement Device (models MyTAP + TAP1)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-01-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-03-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-10-2019
Application type:	Amendment
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

ID: 28622
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL64738.100.18
OMON	NL-OMON28622