Comparison of two mandibular advancement devices in mild to moderate obstructive sleep apnea (OSA) patients: a randomized crossover trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52245

Source
ToetsingOnline

Brief title
CONASO

Condition

- Other condition

Synonym
OSA, OSAS

Health condition

Slaapstoornissen, slaapapneu

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: TKI Health Holland,VIVISOL B.V. ,VIVISOL B.V. and TKI Health Holland

Intervention

Keyword: MAD, Narval, Preference, Somnodent

Outcome measures

Primary outcome

The aim of this study is to compare the Narval CC® and the SomnoDent Flex® in a short-term and long-term follow-up. The primary outcome measures in the short-term and long-term follow-up are:

Short-term follow-up:

Primary outcome measure:

1. Preferred MAD: outcome based on a questionnaire on preference.

Long-term follow-up:

Primary outcome measure:

1. Mean disease alleviation: the product of sleep-time adjusted adherence (subjective oral appliance (OA) use/total sleep time, expressed in percentage) with therapeutic MAD efficacy (AHI baseline minus AHI with OA applied, expressed in percentage), divided by 100.

Secondary outcome

The aim of this study is to compare the Narval CC® and the SomnoDent Flex® in a

short-term and long-term follow-up. The secondary outcome measures in the short-term and long-term follow-up are:

Short-term follow-up:

Secondary outcome measures:

1. Adherence: self-reported number of hours of wearing the MAD per total sleep time, in hours, *100%.

2. Therapy success: the number of patients with an apnea-hypopnea index (AHI) of <5 events/hour of sleep.

3. Quality of life and sleep quality: total score of quality of life questionnaire and that of sleep quality questionnaire.

4. Mean disease alleviation: the product of sleep-time adjusted adherence (subjective oral appliance (OA) use/total sleep time, expressed in percentage) with therapeutic MAD efficacy (i.e., AHI baseline minus AHI with OA applied, expressed in percentage), divided by 100.

5. Side-effects: number and type of side-effects.

6. Clinical performance: number of unexpected visits to the outpatient clinic for their MAD therapy.

Long-term follow-up:

Secondary outcome measures:

1. Adherence: self-reported number of hours of wearing the MAD per total sleep time, in hours *100%

2. Therapy success: the number of patients with an AHI of <5 events/hour of

sleep

3. Quality of life and sleep quality: total score of quality of life

questionnaire and that of sleep quality questionnaire.

4. Orthodontic side-effects: overbite (i.e., it refers to the vertical overlap

between the maxillary central incisors over the mandibular central incisors)

and overjet (i.e., it refers to the horizontal overlap of the maxillary central

incisors over the mandibular central incisors), in mm

5. Clinical performance: number of unexpected visits to the outpatient clinic

for their MAD therapy

6. Costs: the estimated mean total costs in EUR per MAD during study (e.g.,

chair time of each visit, production costs of MAD, costs of reparations,

consult time by phone)

Study description

Background summary

Obstructive Sleep Apnea (OSA) is a condition characterized by repetitive complete or partial obstructions of the upper airway that are often related to oxygen desaturations and arousals from sleep. The prevalence of OSA varies from 9% to 38% in the general adult population, affecting more men than women, primarily in middle-aged, obese individuals. Mandibular advancement devices (MADs) are commonly prescribed for the treatment of mild to moderate OSA patients, and for severe OSA patients who cannot tolerate continuous positive airway pressure (CPAP). The rationale behind the efficacy of MADs is that advancement of the mandible and tongue improves upper airway patency during sleep by enlarging the upper airway and by decreasing upper airway collapsibility, thereby preventing collapse during sleep.

In this study, Narval CC® (ResMed, Lyon, France) and SomnoDent Flex® (SomnoMed, Sydney, Australia) MADs are compared in OSA patients. The main differences in design between these MADs are: 1. the size, weight, and material, which could influence the preference of patients and their adherence to the therapy; and 2.

the couple-mechanism between upper and lower splints, which could result in differences in the appliances* effects on OSA.

Study objective

To our best knowledge, there are no studies on the preference of OSA patients for one or another MAD type based on its design characteristics. Therefore, the main objective of the study is to compare these MADs on the aspect of preference of patients based on the design characteristics of the MAD. The secondary objectives of this study are to compare these MADs on adherence, therapy success, quality of life, mean disease alleviation (MDA), side-effects, clinical performance, and costs.

Study design

Randomized crossover design

Intervention

This study focuses on preference of OSA patients for one or another MAD type by comparing two different types of MADs in a randomized crossover design. The first type is the Narval CC® (ResMed, Lyon, France), which is manufactured by computer-aided design-computer-aided manufacturing (CAD-CAM) technology. The Narval CC®-MAD consists of two splints, fixed on the mandible and the maxilla, and connected to each other with replaceable bars of different lengths for titration (i.e., the MAD gradually places the mandible in a more anterior position for an optimal therapeutic result).The vertical opening is limited by these bars. The second type is the SomnoDent Flex® (SomnoMed, Sydney, Australia), which consists of two splints, fixed on the mandible and the maxilla and allowing free vertical opening. It has a screw mechanism in the upper splint, which is used for titration. The SomnoDent Flex® is manufactured by conventional technology. The impressions will be send to a dental technician and will be used to make a custom-made MAD manually.

Study burden and risks

The risks for patients participating in this study are negligible. Possible common short-term side effects of both MADs may be discomfort in the jaw, temporomandibular joint pain, sensitivity of the teeth, excessive salivation and a dry mouth. Withdrawing from this therapy means an immediate relief of inconveniences in case of the short-term effects. A common long-term side-effect is orthodontic tooth movement. These orthodontic tooth movements are small in the majority of the cases.

As part of their standard care, the patients will undergo an orthopantomogram (OPT) at baseline before the start of MAD treatment. The OPT is made to check

if the dentition is adequate for manufacturing an MAD. This OPT is not used for research purposes. To determine the orthodontic side effects on skeletal level (i.e., to compare the lateral cephalogram at different moments during the course of the treatment with the MAD, and to evaluate orthodontic tooth movement), patients will undergo a lateral cephalogram examination at baseline, at one-year follow up, and at five-year follow up. Both OPT and lateral cephalogram involve the use of radiation and therefore the application of the standard principles for the safe use of radiation is needed. The effective dose of an OPT is about 20µSv; for a lateral cephalogram, about 7µSv. The total effective dose for patients in this study is (1x 20) + (4 x 7) = 48µSv. The International Commission on Radiological Protection (ICRP) 62 has categorized research into four levels, depending upon the radiation dose to be received by each subject [1] (Appendix 1). Our study belongs to category I, which involves risks of 10-6 or less. The risks include cancer and hereditary disorders [2]. Compared with the average risk of cancer and hereditary disorders of the population (1/17,000 and 1/77,000 respectively), the risk in this study is minor according to the ICRP categories.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• 18 years or older;
• Sufficient understanding of Dutch language in speaking, reading, and writing;
• Ability to follow-up;
• Ability to use a computer with internet connection for online questionnaires;
• Diagnosis with symptomatic mild or moderate OSA (5 <= AHI < 30).
• Dentition is adequate for both MADs (e.g., normal dental crown height, normal dental arch)

Exclusion criteria

• Reversible morphological upper airway abnormalities (e.g. enlarged tonsils);
• Previous treatment with an MAD;
• Inability to provide informed consent;
• Simultaneous use of other modalities to treat OSA;
• Known medical history of mental retardation, memory disorders, or psychiatric disorders;
• Evidence of respiratory/sleep disorders other than OSA (e.g., central sleep apnea (CSA));
• Medication usage that has an effect on sleep;
• Untreated periodontal problems, dental pain, and a lack of retention possibilities for both MADs;
• Severe temporomandibular disorders (based on the function examination of the masticatory system).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2022
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-11-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL77762.075.22