Mandibular Advancement Device (MAD) therapy in edentulous patients with obstructive sleep apnea: dental implant fixed MADs vs. CPAP.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON45006

Source
ToetsingOnline

Brief title
MADE-study

Condition

- Upper respiratory tract disorders (excl infections)
- Head and neck therapeutic procedures

Synonym
Obstructive sleep apnea syndrome, sleep apnea

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dental implants, edentulism, mandibular advancement device, obstructive sleep apnea

Outcome measures

Primary outcome

AHI (baseline vs. 3 months): apnea hypopnea Index (AHI) derived from standardized polysomnography studies at baseline and 3 months after CPAP treatment initiation (control-group) or MAD therapy initiation (intervention group).

Secondary outcome

- AHI (baseline vs. 12 months): apnea hypopnea Index (AHI) derived from standardized polysomnography studies at baseline and 12 months after CPAP treatment initiation (control-group) or MAD therapy initiation (intervention group).

- Polysomnography parameters: These parameters include apnoea index (AI), hypopnoea index (HI), desaturation index (DI), snoring index (SI), lowest and mean oxygen saturation (SaO2) and sleep efficiency at baseline, 3 and 12 months after treatment initiation.

- General health: General health parameters will be assessed by measuring body mass index (BMI), blood pressure and neck circumference.

- Functionality of the dentition and jaws: Functionality of the dentition and jaws will be assessed with the standardized MFIQ (Mandibular Function

Impairment Questionnaire) questionnaire at baseline, 3 and 12 months after treatment initiation.

- Sleep health and daily functioning: Sleep health and daily functioning will be assessed with the standardized ESS (Epworth Sleepiness Scale) questionnaire at baseline, 3 and 12 months after treatment initiation.

- Therapy compliance: Patient compliance will be evaluated with a chip integrated in the MADs (monitoring total wearing time with temperature sensors) or monitored by the CPAP devices. A multi-week average compliance (% wearing time >4 hours per night) will be measured at the time period of 3 and 12 months after treatment initiation.

- Mental state: Depression symptoms will be evaluated with the standardized PHQ-9 questionnaire at baseline, 3 and 12 months after treatment initiation.

- Quality of life (QoL): QoL will be measured with the standardized FOSQ-questionnaire at baseline, 3 and 12 months after treatment initiation.

Study description

Background summary

Obstructive sleep apnea (OSA) is a major medical problem, estimated to affect up to 15-30% of the adults in the USA. Characterized by repetitive obstructions of the upper airway during sleep, OSA results in fragmented sleep and excessive daytime sleepiness. Consequences of untreated OSA are serious and include cardio- and cerebrovascular disease, diabetes mellitus, depression, glaucoma and increased all-cause mortality. It is also related to an increased risk of involvement in motor vehicle crashes and a decreased quality of life (QoL). Major risk factors for OSA include male gender, higher age, obesity, smoking and craniofacial abnormalities.

In the Netherlands approximately 41 percent of the individuals older than 65 years are completely edentulous. As a result of morphological changes, a higher

incidence of OSA is reported in (partial) edentate individuals compared to the general population. The exact prevalence of edentulousness in OSA patients is unknown, however this number is likely to be significant and increasing due to the aging population and current rise of obesity.
Continuous positive airway pressure (CPAP) therapy is the current gold standard in OSA therapy next to lifestyle alterations. Although CPAP therapy is widely used in OSA management, it is accompanied with high non-adherence rates up to 80% due to side effects and wearing discomfort. Oral appliance therapy (e.g. mandibular advancement device therapy) is a viable and effective treatment alternative, however requires sufficient dentition for device retention. This results in oral appliance therapy not being usable in up to one third of all OSA patients due to dental limitations. Due to the low CPAP compliance rates, the potential risks of untreated OSA and the lack of other suitable therapies there is an unmet clinical need of effective treatment strategies for edentulous OSA patients.

Very limited evidence is available regarding the outcomes of treatment with MADs or CPAP in edentulous OSA patients. Some case studies showed the potential effectiveness of dental implant retained mandibular advancement device (MAD) therapy in edentulous OSA patients, tackling the major obstacle of poor device retention. An MAD is an intra-oral prosthesis which holds the mandible in a forced protrusive position during sleep, resulting in an increased pharyngeal airway space. Implant retained MADs could potentially tackle the problem of poor device retention in edentulous OSA patients and become a viable treatment option for these patients.
Our hypothesis is that MAD treatment retained on maxillary and mandibular overdentures fixed with 2 mandibular dental implants and 4-6 optionally maxillary implants (based on most recent implantology guidelines NVOI) is an effective treatment strategy in edentulous OSA patients in terms of sleep apnea reduction, wearing comfort/side effects and compliance.

Study objective

The main purpose of this pilot study is to assess the feasibility and potential efficacy of implant retained mandibular advancement device (MAD) therapy on a small scale in edentulous patients with mild to moderate OSA in comparison to CPAP therapy (current standard) in terms of sleep apnea reduction.

Additionally, both treatment will be evaluated in terms of therapy compliance, side-effects, quality of life and complications (e.g. hypertension, depression symptoms). The outcomes of this exploratory study can be used for larger scale hypothesis testing clinical trials on implant retained MAD therapy in edentulous OSA patients.

Study design

Randomized controlled parallel two-group pilot study

Intervention

Participants in this study will be randomly allocated using a block randomization method in one of the two treatment groups:

- Treatment A (intervention)
Mandibular Advancement Device (MAD) therapy; MAD retained on upper and lower overdentures fixed with 2 mandibular dental implants (or pre-existing dental implants). In case of overdenture related complaints during the MAD treatment work-up (e.g. retention problems), treatment can be upscaled with the placement of 4-6 maxillary implants placement (if absent before treatment) to improve retention as part of the regular implant retained overdenture treatment protocol (NVOI Implantology Guidelines 2015).

- Treatment B (control-group)
Continuous Positive Airway Pressure (CPAP) therapy using the standard treatment protocol.

Study burden and risks

Both dental implant retained overdentures, MAD- and CPAP-treatment are well-established treatment that are widely used in daily clinical practice. Burden and risks associated with participation in this study are dependent on the allocated treatment group. General (potential) side effects of MAD therapy include discomfort of the jaw, sensitivity of the maxilla and a dry mouth. Termination of the MAD use would result in quick relief of the above mentioned symptoms.
Dental implant placement (if required) is a routine surgical procedure. All patients undergoing such a procedure are at risk for the general complications associated with dental implants, comprising of infection (peri-implantitis) and bleeding related to the procedure. In case of such events, patients might require additional treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Male of female
- Age 18 * 75 years
- Sufficient understanding of Dutch language in speaking and writing.
- Completely (mandibular and maxillary) edentate with or without dental implants
- Diagnosed with mild or moderate OSA (AHI between 5 * 30)
- No previous OSA therapy

Exclusion criteria

- Craniofacial deformities
- Medication use related to a sleeping disorder
- Evidence of respiratory/sleep disorders other than OSA (eg. central sleep apnea syndrome).
- Reversible morphological upper airway abnormalities (e.g. enlarged tonsils).
- Temporomandibular disorders
- Intravenous bisphosphonates therapy (osteoporosis).
- Previous radiotherapy in head and/or neck area

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	38
Type:	Anticipated

Medical products/devices used

Generic name:	Endosseus dental implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	06-02-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL52980.018.16