

Mandibular advancement device (MAD) therapy in edentulous patients with obstructive sleep apnea: dental implant retained MAD therapy

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Ethical review	Approved WMO
Status	Completed
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON47940

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, Sirona Dentsply

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. - 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. - 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 terms of sleep apnea reduction. Additionally the 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

Non-randomized pilot study

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).

Study burden and risks

Both dental implant retained overdentures and MAD-treatment are well-established treatment that are widely used in daily clinical practice. Burden and risks associated with participation in this study are related to the therapy. 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 or 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 moderate OSA (AHI between 15 - 30) or unsuccessfully treated with CPAP with moderate or severe OSA (AHI > 15) - No

previous OSA therapy, except CPAP

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

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 18-03-2021

Enrollment: 38

Type: Actual

Medical products/devices used

Generic name: Endosseus dental implant and mandibular advancement device

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 25-09-2019

Application type: First submission

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	NL70409.018.19

Study results

Date completed:	01-10-2022
Actual enrolment:	4

Summary results

Trial ended prematurely