A comparison between two different oral appliance therapies: Somnodent vs Herbst appliance in patients with mild and moderate OSA; a Randomised Controlled Trial

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To compare the effect of two different types of mandibular advancement device (MAD) on polysomnographic (PSG) parameters, to evaluate the compliance and to evaluate the outcome of the different Quality of Life scales, eg general health with the...

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

Summary

ID

NL-OMON45035

Source
ToetsingOnline

Brief title
COSH (comparison OSA patients Somnodent vs Herbst)

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
Obstructive 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: MAD (mandibular advancement device), OAT Oral appliance Therapy, Obstructive Sleep Apnea, OSA

Outcome measures

Primary outcome

Primary endpoints: reduction of PSG parameters, in particular Apnoea Hypopnoea Index (AHI), Apnoea Index (AI), Hypopnoea Index (HI), Desaturation Index (DI), and sleep efficiency at baseline, 3 months, and 1 year.

Addendum CBCT:

Primary endpoint: minimum cross-sectional area (CSAmin); mandibular length (me-go).

Secondary outcome

Secondary endpoints: outcome of Quality of Life (QoL) questionnaires; the QoL is measured with questionnaires regarding general health (EQUOL), sleep health and daily functioning (AMCSQ, ESS, FOSQ), and functionality of the dentition and jaws (RDC/TMD and MFIQ) at baseline, 3, 6, 9 and 12 months. Compliance will also be evaluated for the time period of 3, 6, 9 and 12 months

Addendum CBCT:

Secondary endpoints are upper airway size: anterior-posterior (AP) and lateral

(L) dimensions of the CSAmin, and the volume of the upper airway (V); upper

airway shape: 2-D shape of the upper airway (AP/L); and 3-D shape of the upper

airway (CSAmin / CSAavg); face width (tl-tr), anterior neck space area

(ste-cr-ty-cer-me), and cervicomental angle (np-cer-me).

Study description

Background summary

Obstructive sleep apnea (OSA) is a common chronic sleep disorder that often requires lifelong care. The prevalence in the Netherlands is estimated around 300.000 patients. Due to longer life expectancy and increase in weight in the general population, its prevalence is expected to rise. Patients with mild and moderate OSA are treated primarily with an oral appliance at present time. Different oral appliances are available, but most used is the mandibular advancement device (MAD). This study focuses on two different types of MAD: the classic Herbst appliance, which is attached to the mandible and the maxilla and has an iron bar to regulate the open space; and the Somnodent, which consists of two separate splints, fixed on the mandible and the maxilla, but has no iron bar attached.

Addendum CBCT:

Recently, the use of cone beam computed tomography (CBCT) in dentistry has increased considerably. Its high spatial resolution between soft tissue and empty space and its low radiation dose make it an unprecedented method to analyse the upper airway anatomy three-dimensionally. The understanding of the exact working mechanisms of different MADs remains limited. It was suggested that the pattern and magnitude of changes in upper airway anatomy may differ between oral appliances, but more solid data is needed to draw this conclusion. Therefore, large prospective randomized controlled studies are needed to provide more insight into the working mechanisms of different MADs.

Study objective

To compare the effect of two different types of mandibular advancement device (MAD) on polysomnographic (PSG) parameters, to evaluate the compliance and to evaluate the outcome of the different Quality of Life scales, eg general health with the Equol, daytime sleepiness (symptoms) with the Epworth Sleeping Scale (ESS), Functional Outcome of Sleep Questionnaire (FOSQ), jaw pain and function (RDC/TMD and MFIQ) and daily functioning with MAD (OACS)

Addendum CBCT:
The second objective is to determine the difference between *Somnodent* and *Herbst* in their effects on the upper airway morphology.

The third objective is to determine the difference between responders and non-responders to MADs in upper airway anatomy and external craniofacial anatomy at baseline.

Study design

Randomised controlled trial

Intervention

For mild and moderate OSA, the treatment with a MAD is standard therapy. MAD is an intra-oral prosthesis, which holds the mandible in a protrusive position. Because of this position, more pharyngeal space will be available and the AHI (Apnea-Hypopnea-Index) will decrease. Different types of MAD are available, and further research is needed before the physician can make a choice between the different types. In this study, the Somnodent MAD will be evaluated in a RCT with the Herbst appliance. After randomisation, the patient will be allocated to one of the two groups. After 3 months and after 1 year, a PSG is repeated.

Addendum CBCT:
At baseline and after 3 months, CBCT scans will be made at the department of Oral Radiology at ACTA (at baseline without MADs in situ, and after 3 months with MADs in situ). Photographs will be made at baseline at our clinic.

Study burden and risks

The risks for patients participating in this study are negligible. Possible side effects of MAD (Somnodent and Herbst) may be discomfort in the jaw, sensitivity of the teeth, and a dry mouth. Withdrawing from this therapy means immediate relief of inconveniences.

Addendum CBCT:
For NewTom CBCT, the effective doses for large FOVs range from 30~78 µSv, about 50 µSv on average. 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. This study belongs to category I, which involves risks of 10-6 or less. Besides, 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 and could be neglected.

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

+ 18 years and older
+ Ability to speak, read, and write Dutch.
+ 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).
+ Expected to maintain current lifestyle (sports, medicine, diet, etc.)

Exclusion criteria

- Untreated periodontal problems, dental pain, and a lack of retention possibilities for an MAD.

- Medication used/related to sleeping disorders.
- Evidence of respiratory/sleep disorders other than OSA (eg. central sleep apnea syndrome).
- Systemic disorders (based on medical history and examination; e.g. rheumatoid arthritis)
- Temporomandibular disorders (based on the function examination of the masticatory system).
- Medical history of known causes of tiredness by day, or severe sleep disruption (insomnia, PLMS, Narcolepsy).
- Known medical history of mental retardation, memory disorders, or psychiatric disorders.
- Reversible morphological upper airway abnormalities (e.g. enlarged tonsils).
- Inability to provide informed consent.
- simultaneous use of other modalities to treat OSA.
- Previous treatment with a MAD.

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:	Recruitment stopped
Start date (anticipated):	01-03-2016
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	30-07-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Not approved Date:	02-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-06-2015
Application type:	Amendment
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	NL44085.018.13