Measuring the therapy-effect and compliance of a Mandibular Repositioning Appliance (MRA) in patients with mild-to-moderate Obstructive Sleep Apnea Syndrome (OSAS).

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Primary Objective: To determine whether or not our newly developed MRA with accelerometer can measure the therapy-effect of the MRA by determining the correlation of the treatment-efficacy of an MRA measured by an integrated accelerometer built in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON37471

Source
ToetsingOnline

Brief title
Mandibular Repositioning Appliance (MRA) - study

Condition

- Respiratory disorders NEC

Synonym
'OSAS', 'sleep apnea'

Research involving

Human

Sponsors and support

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

Intervention

Keyword: mandibular repositioning, oral appliance, sleep apnea, snoring

Outcome measures

Primary outcome

The Snoring Index (SI), the time the patient is snoring as a percentage of total sleeping time.

Secondary outcome

Compliance: The compliance is calculated based on the accelerometer data from the MRA. From this data the number of nights and the hours per night the MRA is used can be derived.

Position: The position of the head of the patient is calculated based on the accelerometer data from the MRA.

Apneas: The polygraphy can measure the AHI. With the accelerometer-data that is acquired during the second polygraphy we want to see whether or not we can detect apneas with the MRA.

Flow: The polygraphy can measure the airflow during the night. With the accelerometer-data that is acquired during the second polygraphy we want to see

whether or not we can detect the presence and absence of airflow with the MRA.

Quality of life: Health related quality of life changes in patients with OSAS

after MRA-treatment by means of the Quebec Sleep Questionnaire.

Tendency to fall asleep: Change in tendency to fall asleep after the

MRA-treatment by means of the Epworth Sleepiness Scale.

Subjective therapy-effect: Therapy-effect according to the patient and his/her

partner by means of the Visual Analogue Scale.

Study description

Background summary

The diagnosis of Obstructive Sleep Apnea Syndrome (OSAS) is based on the presence of symptoms (e.g. snoring, sleepiness, fatigue and inattention) and the apnea-hypopnea index (AHI). Mild (5 < AHI < 15) to moderate (15 < AHI < 30) OSAS can be treated by means of an MRA which is often the patient*s preferred treatment. The optimisation of MRA treatment (finding the optimal protrusion) may require up to 6 months of progressive mandibular advancement and for assessing the treatment effect a polygraphy is required. Such a polygraphy is very expensive and time-consuming. Also there is night-to-night variation in the severity of sleep apnea and a night sleep in the hospital does not give a good representation of a night sleep in the patient's home environment. In this study we introduce an MRA integrated with an accelerometer to objectively measure compliance, position and breathing patterns like snoring in the patient's home environment.

Study objective

Primary Objective:
To determine whether or not our newly developed MRA with accelerometer can measure the therapy-effect of the MRA by determining the correlation of the treatment-efficacy of an MRA measured by an integrated accelerometer built in

the MRA, with the treatment-efficacy measured by a polygraphy and questionnaires.

Secondary Objective(s):
Determining the compliance of the MRA by comparing its accelerometer data with the compliance diary.

Determining the effect of head-position on the SI.

Study design

This study concerns a comparative study in which the snore index (SI) measured by the MRA will be compared with the SI measured by the polygraphy. Patients can be included in the study at any moment in time, until one month prior to the end of the study.

Prior to the selection the patient is diagnosed having OSAS by conducting a polygraphy that is part of the regular diagnostic process and will be used as a base line measurement. When patients satisfy inclusion, an MRA will be fitted.

Therapy with the MRA will be applied for one month for this study and sequentially a second polygraphy is conducted to assess the efficacy of the therapy. The accelerometer-data from the MRA will also be used to asses the compliance and position of the head.

Intervention

Each individual receives a custom made MRA with an integrated accelerometer and will sleep with the MRA every night during one month.

Subjects who participate in this study will sleep with a custom-made MRA during one month. The first two weeks the subject will use the normal MRA, to get used to the MRA. After the second week an accelerometer will be integrated in the MRA, with which the compliance can be measured during the third and fourth week. The accelerometer will also measure the therapy-effect and the position of the head during the night.

Study burden and risks

Not applicable.

Contacts

Public

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Scientific

Medisch Spectrum Twente

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

* 18 years or older.
* Ability to understand, read and write Dutch.
* Diagnosis of symptomatic mild or moderate OSAS (5 < AHI < 30).
* Eligible for MRA treatment.
* Minimum of eight teeth in each of the maxillary and mandibular arches to support the MRA and prior acceptance by a dentist as suitable patient for MRA therapy.

Exclusion criteria

- Temporomandibular joint disorder.
- Blocked nose
- BMI >= 30
- Restricted mobility of the mandibula

- The inability to provide informed consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2012
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Mandibular Repositioning Appliance
Registration:	No

Ethics review

Approved WMO

Date:	06-03-2012
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL39098.044.12