Measuring the therapy-effect of a mandibular repositioning appliance (MRA): A new method.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26447

Source
Nationaal Trial Register

Brief title
MRA-study

Health condition

mild-to-moderate Obstructive Sleep Apnea Syndrome (OSAS)

Sponsors and support

Primary sponsor: Medical Spectrum Twente, Enschede
Source(s) of monetary or material Support: University of Twente

Intervention

Outcome measures

Primary outcome

Snoring Index (SI): The time the patient is snoring as a percentage of total sleeping time. Measured with the polygraph and the acceleratorsensor.

Secondary outcome

1. 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. The measured compliance is then compared to the outcome of the compliance diary;

2. Position of the head of the patient: The position of the head of the patient is calculated based on the accelerometer data from the MRA. We distinguish three positions: supine, right and left. The supine position means that the head of the patient faces the ceiling. The right and left positions mean that the patient is lying respectively on their right and left side of the head.

Study description

Background summary

We developed a mandibular repositioning appliance (MRA) with an integrated accelerometer for the treatment of mild-to-moderate obstructive sleep apnea syndrome (OSAS). By means of the accelerometer we plan to measure the therapy-effect of the MRA, the compliance and the position of the head. We therefore measure the therapy-effect by means of the amount of snoring (the snoring index (SI)).

Study objective

We developed an MRA with integrated accelerometer with which we plan to measure the therapy-effect of the MRA, the compliance and the position of the head of the patient.

Study design

4 weeks.

Intervention

Therapy with a mandibular repositioning appliance. The appliance is equipped with an acceleratorsensor, which can measure vibrations. A polygrafy will also be performed the same night, to record snorring.

Patients are their own controls.

Contacts

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Eligibility criteria

Inclusion criteria

1. 18 years or older;

2. Ability to understand, read and write Dutch;

3. Diagnosis of symptomatic mild or moderate OSAS (5 < AHI < 30);

4. Eligible for MRA treatment;

5. 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

1. Temporomandibular joint disorder;

2. Blocked nose;

3. BMI ≥ 30;

4. Restricted mobility of the mandibula;

5. The inability to provide informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2012
Enrollment:	15
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL3159
NTR-old	NTR3303
Other	METC Twente / CCMO : P12-08 / NL39098.044.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A