Predicting the success of mandibular advancement device therapy in obstructive sleep apnea

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22428

Source
NTR

Brief title
PRESMO

Health condition

Obstructive sleep apnea
Obstructiefslaapapneu
Mandibular advancement device (MAD)
Mandibulair repositie apparaat (MRA)

Sponsors and support

Primary sponsor: Amphia hospital, Breda, the Netherlands
Source(s) of monetary or material Support: Amphia hospital, Breda, the Netherlands

Intervention

Outcome measures

Primary outcome

• decrease in AHI of at least 50% and AHI< 10/hour, OR

• decrease in AHI below 5/hour if baseline AHI was < 10/hour

Secondary outcome

Decrease in ESS questionnaire, adverse effects, therapy score (1-9), any change in AHI, FOSQ questionnaire, SF-36 questionnaire, compliance.

Study description

Background summary

Obstructive sleep apnea (OSA) is the most common sleep-related breathing disorder. It is characterized by partial or complete collapse of the upper airway. This collapse can be caused by multiple factors, including craniofacial anatomy, soft tissue characteristics, age, obesity and gender. There are multiple treatment options, including surgical procedures, oral appliances and continuous positive airway pressure (CPAP). Treatment with a mandibular advancement device (MAD, also known as mandibular repositioning appliance (MRA), has been extensively described. The choice for using an MAD for treating symptomatic OSA is usually based on the severity of the disease (expressed in the apnea-hypopnea index (AHI) and on the state of dentition. Whether the MAD is effective in treating OSA in an individual patient can only be assessed after multiple months of using the MAD. Until now we do not know which patient characteristics at baseline can predict when treatment with an MAD is effective. As such, improving phenotyping of patients before starting therapy with MAD can be a major improvement in the treatment of symptomatic OSA.

The primary objective of our study is to define a set of patient characteristics that can predict the effectiveness of an MAD in treating symptomatic OSA. The aim of our study is to develop a prediction model to calculate the success rate in an individual patient, that can be applied in daily practice.

We will perform a multi-centre, prospective observational study, including at least 380 patients during a time period of 6 to 12 months. Using multiple and logistic regression analysis we will identify predictors of effective treatment of symptomatic OSA using MAD.

Study objective

The primary objective of our study is to define a set of patient characteristics that can predict the effectiveness of an MAD in treating symptomatic OSA. The aim of our study is to develop a prediction model to calculate the success rate in an individual patient, that can be applied

in daily practice.

Study design

Baseline, visit 3 months after baseline, possible visit 6 months after baseline (if MAD therapy is unsuccessful after 3 months)

Intervention

Multiple questionnaires

Control polygraphy

Lateral cephalogram

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

• 18 years or older at time of inclusion

• Established OSA (AHI of 5/hour or more on poly(somno)graphy)

• Symptomatic OSA (ESS-score > 10)

Exclusion criteria

• patients with dental status hindering the use of MAD such as periodontal and dental problems, severe temporomandibular disorders. Patients with dental implants are allowed to participate.

• patients who cannot be properly instructed on the use of MAD, including patients with mental illness

• presence of complete nasal obstruction

• presence of a tumour in the upper airways

• adenotonsillar hypertrophy grades 3 and 4

• body mass index > 40kg/m2

• presence of obesity hypoventilation syndrome

• presence of any neuromuscular disorder

• chronic obstructive lung disease (COPD) with documented hypercapnia

• central sleep apnea component of > 50% of total AHI

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2019
Enrollment:	380
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-01-2019

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48663
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7458
NTR-old	NTR7700
CCMO	NL65332.100.18
OMON	NL-OMON48663

Study results