Predicting the success of mandibular repositioning appliance therapy in obstructive sleep apnea

Published: 11-12-2018
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON48663

Source
ToetsingOnline

Brief title
PRESMO

Condition

- Sleep disturbances (incl subtypes)

Synonym
OSAS, sleep apnea

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: subsidie wordt aangevraagd bij ZonMW,subsidie wordt aangevraagd bij Amphia Academie

Intervention

Keyword: MAD, OSA, OSAS

Outcome measures

Primary outcome

effective treatment with MRA is described as a reduction in AHI of at least 50%

combined with an AHI< 10. If AHI at baseline was < 10, the index must decrease

to at least < 5.

Secondary outcome

not applicable

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 repositioning appliance (MRA) has been extensively described. The choice for using an MRA 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 MRA is effective in treating OSA in an individual patient can only be assessed after multiple months of using the MRA. Until now we do not know which patient characteristics at baseline can predict when treatment with an MRA is effective. As such, improving phenotyping of patients before starting therapy with MRA can be a major improvement in the treatment of symptomatic OSA.

Study objective

the primary objective of our study is to define a set of patient characteristics that can predict the effectiveness of an MRA 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

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 MRA.

Study burden and risks

since MRA is already a standard treatment option for OSA patients, it poses no significant risks for participants in this study besides known side effects of MRA therapy. While especially in patients with severe OSA, CPAP is often the preferred first therapeutic option, it has not been established that MRA cannot provide an effective treatment in this group. Treatment with MRA may however lead to more frequent visits, since the device needs to be titrated to achieve maximal effectiveness. All study participants will need to undergo a lateral cephalogram for measuring of craniofacial features and a second and possibly a third poly(somno)graphy (PG) to measure the AHI while sleeping with an MRA.

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 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 MRA such as less than 10 teeth per dental arch, 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 MRA, 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: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-07-2019
Enrollment:	380
Type:	Actual

Medical products/devices used

Generic name:	Mandibulair advancement device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-12-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-02-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-10-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22428
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL65332.100.18
OMON	NL-OMON22428