Are pulmonary function test suitable to support the choice for a dental brace treatment in patients with sleep apnea?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22296

Source
NTR

Brief title
PUMA

Health condition

Obstructive Sleep Apnea
Mandibular Advancement Thearpy

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Postbus 50 000
7500 KA Enschede
053 487 20 00
Source(s) of monetary or material Support: initiator sponsor

Intervention

Outcome measures

Primary outcome

The diagnostic accuracy, expressed as sensitivity, specificity, negative predictive value and positive predictive value, for the different measurement parameters. The parameters of the different measurements are:

- Spirometry: absolute difference between the ratios of the expiratory flow rate at 50% of vital capacity to the inspiratory flow rate at 50% of vital capacity (MEF50:MIF50) obtained by the MAD in maximal retracted and maximal protrusive position.

- FOT: absolute difference between the mid-frequency resistances (R20) obtained by the MAD in maximal retracted and maximal protrusive position.

- NEP: absolute difference in flow drops ($\Delta\dot{V}$) as a percentage of the peak flows (%Vpeak) obtained by the MAD in maximal retracted and maximal protrusive position.

Secondary outcome

- The diagnostic accuracy of the different primary measurement parameters with the relative differences instead of the absolute differences between the prediction of MAD success.

- The experience of the subjects with the different tests. This will be evaluated with three questions.

- The diagnostic accuracy of the other spirometry parameters (FVC, FIVC, FIV1, FEV1, ‘saw toothing’, MEF50, MIF50, VC) for successful MAD therapy, by both calculating the absolute and relative differences between the results obtained by a MAD in maximal retracted and maximal protrusive position.

- The diagnostic accuracy of the other FOT parameters (R5, X5, R5-20, fres, AX) for successful MAD therapy, by both calculating the absolute and relative differences between the results obtained by a MAD in maximal retracted and maximal protrusive position.

- The diagnostic accuracy of the V0.2 of the NEP measurement as a percentage of the mean inspiratory volume of the 3 breaths preceding NEP and as a percentage of the mean expiratory volume during the first 0.2 s of the 3 breaths preceding NEP for successful MAD therapy. This is performed by both calculating the absolute and relative differences between the results obtained by a MAD in maximal retracted and maximal protrusive position.

- The diagnostic accuracy of the percentage of expired tidal volume over which the NEP-induced flow did not exceed spontaneous flow (%EFL) for successful MAD therapy, by both calculating the absolute and relative differences between the results obtained by a MAD in maximal retracted and maximal protrusive position.

- Additional study parameters are obtained by performing an explorable analysis on the spirometry, FOT and NEP data. The diagnostic accuracy of these parameters as for successful MAD therapy are determined by both calculating the absolute and relative differences between the results obtained by the mandible maximal retracted and maximal protruded.

- The diagnostic accuracy of the different primary and secondary measurement parameters for an alternative definition of MAD success. This definition is also based on the control poly(somno)graph after the titration period of the MAD and is defined as an AHI < 10 with reduction of complaints.

- The coherence of the absolute and relative differences in all the above-mentioned study parameters and the absolute and relative decrease in AHI between the first and control poly(somno)graph.

Study description

Background summary

In this study, 25 patients with obstructive sleep apnea (OSAS) are included. An adjustable mouthpiece will be applied during three different pulmonary function tests: a spirometry, a forced oscillation technique (FOT) and a negative expiratory pressure (NEP). The measurements are performed twice while the subject is lying on his/her back; with the mandible completely protruded and with the mandible completely retracted. The main study objective is to investigate the diagnostic accuracy, expressed as the sensitivity, specificity, negative predictive value and positive predictive value of resistance and flow parameters obtained by spirometry, FOT, and NEP both in protrusion and retraction of the mandible in OSAS patients for the prediction of successful MAD therapy compared to a poly(somno)graph

Study objective

The difference in resistance and flow parameters obtained by spirometry, forced oscillation technique (FOT) and negative expiratory pressure (NEP) in protrusion and retraction of the mandible in OSAS patients are predictive parameters for successful mandibular advancement device (MAD) therapy.

Study design

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Intervention

Patients will visit the hospital where the three measurements will be performed. Before the measurements are performed, the demographic data is obtained. The measurements are divided into three different measurements: the forced oscillation technique (FOT), negative expiratory pressure (NEP) and the spirometry. During the measurements the patients is wearing an adjustable mouthpiece to enable protrusion and retraction of the mandible. All the measurements are perfored with the mandible in the maximal comfortable retracted and maximal comfortable protrusive position. The measurements are performed while the patient is laying on his back on a flat examination bench with the legs uncrossed. After the three

different measurements in lying position, a standard spirometry in sitting position is performed. The vital capacity is measured and also the forced vital capacity during a forced maximal inspiration and expiration. At the end the patient is asked to answer some questions to evaluate their experience with the different measurements.

Contacts

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Eligibility criteria

Inclusion criteria

Obstructive Sleep Apnea (OSAS) patients with an age of ≥ 18 years.

Apnoea-hypopnoea index (AHI) ≥ 15

Signed informed consent prior to participation.

Scheduled a control poly(somno)graph after titration of mandibular advancement device (MAD) therapy.

Exclusion criteria

Inability to read and/or understand the Dutch language.

Having a control polygraph after an initial polysomnography

Having a control polysomnography after an initial polygraph

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2019
Enrollment:	25
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-12-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48021
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7441
NTR-old	NTR7683
CCMO	NL67820.044.18
OMON	NL-OMON48021

Study results

Summary results

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