

Drug-induced Sleep Endoscopy: a prediction tool for success rate of oral appliance treatment

No registrations found.

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

Summary

ID

NL-OMON20741

Source

NTR

Brief title

Pre-dot trial

Health condition

Obstructive Sleep Apnea

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Poly(somno)graphy 6 months after treatment (AHI, ODI 3%,...)

Secondary outcome

Quality of life: ESS and FOSQ-30

Patients' complaints

BMI

Complications: temporomandibular dysfunction, dental problems,...

Study description

Background summary

A prospective cohort study of consecutive patients diagnosed with obstructive sleep apnea with an apnea-hypopnea index between 15-30. Drug-induced sleep endoscopy is performed before oral appliance treatment. Patients will be included into a positive- or negative- jaw thrust maneuver group. Both patients with a positive and negative chinlift will be included for oral appliance treatment. Primary outcome will be poly(somno)graphy (AHI) 6 months after treatment, compared to poly(somno)graphy (AHI) at diagnosis. Secondary outcomes will be quality of life measured by the ESS and FOSQ-30 questionnaire, patients' complaints, BMI and complications.

Study objective

Drug-induced Sleep Endoscopy with concomitant jaw thrust maneuver is a suitable predictor for success of oral appliance treatment.

Study design

Start: 1 december 2019

Stop: 1 december 2020

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

- Patients of 18 years and older with obstructive sleep apnea confirmed by poly(somno)graphy
- Apnea-hypopnea index between 15 and 30
- BMI < 35

Exclusion criteria

- Dentition not suitable for OAT
- Other dental problems, e.g. temporomandibular dysfunction, micrognathia

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2019
Enrollment:	80
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 03-03-2020

Application type: First submission

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	NL8425
Other	MEC-U : W19.133

Study results