Transoral robot surgery of the tongue base vs. Continuous positive airway pressure or mandibular advancement device as a treatment for moderate to severe obstructive sleep apnea.

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The primary objective of this study is to objectify the efficacy of TORS compared to CPAP and MAD. Secondary objectives:To determine long term outcomes of TORS compared to CPAP or MAD.To compare functional sleep outcomes in TORS and CPAP/MAD...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56291

Source
ToetsingOnline

Brief title
RAPID

Condition

- Other condition
- Head and neck therapeutic procedures

Synonym
obstructive sleep apnea, sleep disorder

Health condition

obstructieve slaap apneu

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Via interne fondsen van het MCL

Intervention

Keyword: CPAP, MAD, Robotics, Sleepapnea

Outcome measures

Primary outcome

The primary outcome measure is a PSG measurement, the apnea-hypopnea index (AHI) at 6 months.

Secondary outcome

Secundary study parameters:

• To establish whether TORS long term outcomes of 12 months are superior to CPAP and MAD in terms of AHI.

• To compare other outcomes of the PSG such as ODI 4% at 6 and 12 months in TORS and CPAP/MAD patients.

• To compare functional outcome of sleep after TORS to CPAP and MAD through ESS questionnaire at 12 months.

• To evaluate surgical complications after TORS.

• To evaluate health related quality of life in TORS group versus CPAP/MAD group via FOSQ, EQ-5D-5L and GBI questionnaires.

• To assess costs of TORS and CPAP and MAD treatment.

• To assess CPAP and MAD compliance via read out of CPAP and consultations via pulmonologist and maxilla facial oral surgeon.

• To systematically measure and analyse relevant surgical parameters such as operative time, length of hospital stay and to evaluate the effectiveness and efficiency of TORS and thereby optimizing surgical practices.

• To assess post-operative pain levels after TORS via VAS pain scores at baseline, after surgery, day 1, day 3 or 4 and the day of discharge.

• To assess swallowing quality after TORS via VAS scores for swallowing, swallowing questionnaires at baseline, 3, 6 and 12 months and via assessment by language speech pathologist at baseline, 2 days post-surgery and 6 weeks.

• To determine differences in VAS scores for snoring, tiredness and globus at baseline, 3, 6 and 12 months between TORS group and CPAP/MAD group.

• To establish baseline descriptive characteristics and variables of the study population in terms of findings during ENT examination, BMI, history of smoking and reflux.

Study description

Background summary

In Obstructive Sleep Apnea (OSA) there is repeated partial or complete obstruction of the upper airway, leading to hypoxia and fragmented sleep. OSA is usually caused by multilevel collapse of the upper airway, with the tongue base being the most common site of collapse. The prevalence is estimated to be 23,4% in women and 49,7% in men over the age of 40. Based on research by the Apnea Association in 2015, the number of newly diagnosed OSA patients in the Netherlands is estimated to be 40,785 per year. The overall prevalence of OSA in the Netherlands is estimated to be 600,000 patients. OSA has a significant effect on the overall health of patients. Hypertension, stroke, cardiovascular disease, cognitive dysfunction, diabetes mellitus type 2 and arrhythmias are much more common in patients with OSA. There is also an association between the number of traffic accidents/deaths and OSA. The 5-year mortality rate of adults with untreated OSA is increased by 30%. The gold standard treatment for OSA is continuous positive airway pressure (CPAP). This is an effective treatment.

Nonetheless, 30% of patients refuse CPAP treatment. As it is generally accepted that CPAP is only effective when used for more than 4 hours per night and in at least 70% of nights, patient compliance remains a challenge. After 6 months, in only 50% of the patients CPAP is used for more than 4 hours per night and after 5 years this percentage drops to only 17%. Secondary to CPAP are the mandibular advancement devices (MAD) which move the mandible and or tongue ventrally which opens the upper airway and reduces its collapsibility during sleep. Like CPAP, the effectiveness of MAD depends on patient compliance. Surgery offers a great advantage over conventional treatment as it offers the possibility to resolve apneas and hypopneas and avoid lifelong use of CPAP or MAD without the problem of poor patient compliance. Reduction of the tongue base via trans oral robotic surgery (TORS) is an accepted and well tolerable treatment for OSA in patients with collapse at tongue base site. The robot technique has shown to increase surgical precision and more delicate handling of tissues. However, to this day, it remains unclear if TORS has a higher efficacy compared to the non-surgical gold standard CPAP and frequently used MAD. In addition, long-term effects of TORS remain unclear. We hypothesize that TORS could be superior to conventional treatment modalities in terms of improving sleep, overall health and quality of life. Herewith, we present a research protocol for a prospective randomized controlled trial that allows us to examine if tongue base reduction via TORS has a superior outcome to the gold standard treatment CPAP and MAD in patients with moderate to severe OSA.

Study objective

The primary objective of this study is to objectify the efficacy of TORS compared to CPAP and MAD.
Secondary objectives:
To determine long term outcomes of TORS compared to CPAP or MAD.
To compare functional sleep outcomes in TORS and CPAP/MAD patients.
To determine TORS surgical complications.
To evaluate health-related quality of life in both groups.
To assess the cost of TORS compared to CPAP and MAD.
To assess patient compliance of CPAP and MAD.
To evaluate post-operative pain after TORS.
To evaluate swallowing quality after TORS.

Study design

This study will be a randomized controlled trial.

Intervention

Group 1 will contain 25 patients that will receive TORS as treatment of OSA.
Group 2 will contain 25 patients that will receive standard treatment via CPAP

or MAD depending on what patient and physician prefer.

Study burden and risks

Patients participating in this study will not impose any extra burden deviating from the usual risks of standard care for OSA. Patients will visit the hospital at 3 months, 6 months and 12 months for follow up and evaluation of treatment. Study measurements will be collected during regular hospital visits. If patients are randomized into the TORS group, they have the advantage of only receiving one treatment compared to the conservative group, who will be treated with CPAP or MAD every day over the course of the study. The disadvantage of the TORS group is a chance of experiencing known complications associated with surgery, such as bleeding and infections, which may result in a longer post-surgery hospital stay. Furthermore, 3 quality of life, 1 sleep questionnaire and 1 swallowing quality questionnaire are taken and are short so will not impose a substantial burden on patients. As TORS as well as CPAP and MAD are approved treatment modalities, there are no advantages over standard care. Study participation will no longer enable patient and physician to choose the treatment modality at first as it will be chosen through randomization. However, after study participation, all treatment options are available when indicated. Patients will not receive compensation for participating in the study. No extra hospital visits are required to participate in the study.

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

- Participant has to be 18 years or older.
- Participant should understand study protocol.
- Apnea hypopnea index (AHI) during polysomnography (PSG) equal to 15 or higher.
- During physical examination tongue tonsil of Friedman grade 3 or 4.
- During sleep endoscopy collaps of tongue base level grade 2.

Exclusion criteria

- BMI of 32 or higher.
- During sleep endoscopy concentric collaps.
- Symptoms of central sleep apnea syndrome (CSAS).
- Participants with ASA score of 4.
- Excessive use of opiates and benzodiazepines.
- History of treatment with CPAP or not tolerating of MAD.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-07-2024
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Da Vinci robot;CPAP;mandibular reposition device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-09-2023
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
CCMO	NL84446.099.23