cost-effectiveness of obstRuctivE Sleep apnea Therapy (REST study): Comparison of MRA therapy versus CPAP therapy in moderate OSAS

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To compare the cost-effectiveness and effectiveness of MRA therapy versus CPAP therapy in patients with moderate OSAS.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON41520

Source
ToetsingOnline

Brief title
REST study

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
OSAS, Sleep apnea syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: SomnoMed Goedegebuure,VitalAire

Nederland BV,VitalAire Nederland BV / SomnoMed Goedegebuure

Intervention

Keyword: Cost Effectiveness, Obstructive Sleep Apnea Syndrome, Treatment Outcome

Outcome measures

Primary outcome

Incremental cost-effectiveness ratio (ICER) in terms of AHI reduction measured during polysomnography and quality adjusted life years (QALYs).

Secondary outcome

Polysomnographic outcomes: total sleep time, sleep efficiency, minimal oxyhemoglobin saturation, arousals, sleep stages; anthropometrical outcomes: BMI, waist and neck circumference, fat-free mass and fat percentage; objective and subjective side effects; neurobehavioral outcomes (by questionnaires): EDS, quality of life, anxiety and depression, activities of daily living, compliance, satisfaction; cardiovascular risk: smoking status, ambulant blood pressure measurements, blood samples, urine sample, accumulation of advanced glycation endproducts (AGEs) in skin tissue.

Study description

Background summary

Obstructive sleep apnea syndrome (OSAS) is an underdiagnosed, undertreated and highly prevalent disease (4% of middle-aged men and 2% of women). It is characterized by repetitive upper airway collapse during sleep, disruptive snoring and excessive daytime sleepiness (EDS). OSAS is defined by a combination of these symptoms and laboratory findings. Laboratory findings should demonstrate an apnea-hypopnea index (AHI) of five or more. As obesity is the most important risk factor for OSAS and the number of people with obesity is increasing, the prevalence as well as the incidence of OSAS will almost

certainly increase even further, as is clear already in the USA. Moreover, OSAS is an important risk factor for sick leave, work disability, cardiovascular co-morbidities, and becoming involved in traffic accidents. Appropriate treatment will subsequently reduce these symptoms and co-morbidities. Given the large impact on patients in terms of health and society in terms of costs, cost-effective treatment is necessary.
According to the CBO guideline *Diagnostics and treatment of the obstructive sleep apnea syndrome in adults*, in moderate OSAS both MRA and CPAP can be considered as primary interventions as both are proven to be effective in reducing the AHI. Although MRA is generally considered less effective than CPAP, it was shown that MRA is not inferior to CPAP regarding AHI in non-severe OSAS and that many patients report greater satisfaction with MRA.
Cost-effectiveness of CPAP and MRA is only documented on EDS in the USA and Canada. Therefore, proper cost-effectiveness analysis with AHI as primary outcome in this specific OSAS group in the Netherlands is still needed.

Study objective

To compare the cost-effectiveness and effectiveness of MRA therapy versus CPAP therapy in patients with moderate OSAS.

Study design

In a randomized parallel controlled study patients will be randomly assigned to either MRA therapy or CPAP therapy. Group A receives MRA. Group B receives CPAP. Both treatment periods last for 12 months. The total duration of the study is 12 months. Measurements will be done at baseline, after 3, 6 and 12 months.

Intervention

Patients in group A are treated with a bibloc MRA (SomnoDent). It positions the patient's mandible in a forward and downward position thereby *stretching* the upper airway. The mandible will be set at 70% of the patient*s maximum advancement and will be adjusted to the convenience of the patient. Titration will be continued until symptoms abate or until further advancement causes discomfort.
Patients in group B are treated with CPAP therapy. The proper CPAP-pressure is set for each patient separately. Patients are fitted
with a comfortable CPAP mask before titration of the CPAP-pressure. For CPAP-titration, patients are instructed to adopt their
own typical sleeping habits.

Study burden and risks

The burden for the patient will be the time investment (visits to outpatient

center, filling in diary and questionnaires), and undergoing medicial examinations (primary and secondary outcomes).
During the initial period of use of MRA patients commonly report discomfort of the teeth and jaws, gum irritation, excessive salivation or a dry mouth. Mild pain of the masticatory muscles and temporomandibular joint often occur. In many cases the adverse effects are transient and disappear with continued use. One of the main problems encountered in patients using CPAP is pressure-related discomfort or intolerance. Patients complain about nocturnal awakenings, claustrophobia, mouth and mask leak and nasal problems, such as dryness, congestion, rhinorrhea and sneezing.

Benefits of the treatments could be a reduction in AHI, reduction of EDS, improvement in quality of life, and on the long term reduction in cardiovascular risk.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Individuals with moderate (AHI 15-30) OSAS, measured during polysomnography
2. Aged >18 years

Exclusion criteria

Medical and psychological criteria:
1. Patients previously treated for OSAS (CPAP, MRA);
2. Morphologic abnormalities of the upper airway (e.g., a compromised nasal passage, enlarged tonsils or adenoids, or upper airway soft-tissue or craniofacial abnormality);
3. Reported or documented unstable endocrine dysfunction (hypothyroidism, acromegaly, or pituitary adenoma);
4. Reported or documented severe cardiovascular- or pulmonary co-morbidity
- coronary disease, heart failure, severe cardiac arrhythmias
- CVA within 6 months prior to randomisation
- daytime respiratory insufficiency
- severe Chronic Obstructive Pulmonary Disease (COPD) (GOLD 3 or 4; FEV1/FVC<70% and FEV1 <50%);
- other diseases that may impact the evaluation of the results of the study according to the investigator's judgement
5. Reported or documented psychological condition precluding informed consent (e.g., mental retardation, depression or schizophrenia);;Dental exclusion criteria:
1. Extensive periodontal disease or tooth decay;
2. Active temporomandibular joint disease (including severe bruxism);
3. Restrictions in mouth opening (<25mm) or advancement of the mandible <5mm);
4. Partial or complete edentulism (less than eight teeth in upper or lower jaw).

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:	Recruitment stopped
Start date (anticipated):	03-05-2012
Enrollment:	86
Type:	Actual

Medical products/devices used

Generic name:	Continuous Positive Airway Pressure (CPAP)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-03-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT01588275
CCMO	NL34138.042.10

Study results

Date completed:	31-12-2017
Actual enrolment:	86