Prospective cohort study on the effect of surgical treatment of obstructive sleep apnea syndrome on blood pressure (and other cardiovascular risk factors).

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In The Netherlands 2% of women and 4% of men suffer from Obstructive Sleep Apnea Syndrome (OSAS). NCPAP, the gold standard therapy for moderate to severe OSAS has been shown to reduce blood pressure in OSAS. NCPAP therapy is however hampered by…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON30534

Source
ToetsingOnline

Brief title
ESTOSASBP

Condition

- Other condition
- Upper respiratory tract disorders (excl infections)
- Respiratory tract therapeutic procedures

Synonym
obstructive sleep apnea syndrome, sleep disordered breathing

Health condition

bloeddruk

Research involving
Human

Sponsors and support

Primary sponsor: Sint Lucas Andreas Ziekenhuis
Source(s) of monetary or material Support: subsidie aangevraagd bij Nederlandse Hart Stichting

Intervention

Keyword: bloodpressure, OSAS, risk factors, surgery

Outcome measures

Primary outcome

The primary endpoint is the change in the average 24 hour mean arterial blood

pressure at 6 months relative to baseline.

Secondary outcome

Secundary study parameters include change in cholesterol levels at 6 months

relative to baseline.

Study description

Background summary

Obstructive sleep apnea syndrome (OSAS) is the most common sleep disorder and increasingly recognised as a major health problem. The prevalence of OSAS in the middle aged population is 2% of women and 4% of men. (1) In the Netherlands 40,000 men and 20,000 women suffer from OSAS. (2) It*s estimated that 80% of OSAS patients remains undiagnosed (3).
OSAS is defined by the American Academy of Sleep Medicine Task Force (1999) as more than five obstructive apneas or hypopneas per hour of sleep and excessive daytime sleepiness, not explained by other factors, or two or more of the following symptoms: gasp for breath during sleep, repeated nocturnal awakening, non recuperative sleep, diurnal fatigue and altered concentration. (4) The severity of OSAS is expressed in the apnea hypopnea index (AHI). An AHI of 5-15 is mild OSAS, an AHI of 15-30 is moderate and AHI >30 is severe OSAS, as assessed by polysomnography. (5)

The chief pathophysiological event is abnormal narrowing of the upper airway during sleep and loss of tone in the pharyngeal muscles. OSAS is being treated because of its complaints, but also since it is becoming increasingly clear that OSAS is associated with considerable comorbidity, including hypertension and increased risk for other cardiovascular diseases. Nocturnal and daytime blood pressure are raised in patients with OSAS. This effect is independent of obesity and other risk factors for raised blood pressure (6-10).
Treatment of OSAS consists of lifestyle alterations, as weight reduction in case of overweight, and abstinence of alcohol, sedatives and sleep medication. Non-invasive treatment consists of the use of a mandibular repositioning appliance (MRA) in mild to moderate OSAS. The *golden standard* treatment of moderate to severe OSAS is nasal continuous positive airway pressure (nCPAP). NCPAP acts as *pneumatic splint*, keeping the upper airway open during sleep. A randomised parallel trial in which therapeutic and sub-therapeutic nCPAP in men with OSAS were compared showed that therapeutic nCPAP reduced mean arterial ambulatory blood pressure by 2.5 mm Hg. In patients with most severe sleep apnea, nCPAP reduces blood pressure providing significant vascular risk benefits. (11) Unfortunately, 40% of OSAS patients can*t tolerate nCPAP therapy for a variety of reasons.
Surgical treatment for OSAS aims to relieve the obstruction. The principal interventions are:
1) Nose and sinus surgery to increase nasal passage, in case of decreased nasal passage;
2) If the obstruction is on palate-uvula-tonsil level, therapeutic options consist of radiofrequent ther-motherapy, laser-assisted uvuloplasty, uvulopalatopharyngoplasty (UPPP), with or without tonsillectomy;
3) while in retrolingual obstruction surgical options are radiofrequency of the tongue base or hyoid sus-pension. In case of severe OSAS and multilevel obstruction, multilevel surgery in one tempo is increasingly performed. (2)
So far no studies have been performed assessing the effect of successful surgical treatment of OSAS on blood pressure and other cardiovascular parameters in patients with moderate to severe OSAS.

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Study objective

In The Netherlands 2% of women and 4% of men suffer from Obstructive Sleep Apnea Syndrome (OSAS). NCPAP, the gold standard therapy for moderate to severe OSAS has been shown to reduce blood pressure in OSAS. NCPAP therapy is however hampered by compliance issues; 40% of patients will not use it in the long run, others use it for only a few hours/night and/or not 7days/week. Results of surgery for OSAS are improving. The effects of surgery on cardiovascular parameters have not yet been studied. If surgery leads to a sufficient lowering of the AHI, the effect is present 7 nights per week. We want to study blood pressure, lipids spectrum and fasting glucose level preoperative and 3 and 6 months postoperative in patients with moderate to severe OSAS who undergo surgery. In this way we will be able to evaluate the effect of successful OSAS surgery on cardiovascular risk.

Study design

Prospective cohort study.

Intervention

OSAS surgery; the principal interventions are:
1) Nose and sinus surgery to increase nasal passage, in case of decreased nasal passage;
2) If the obstruction is on palate-uvula-tonsil level, therapeutic options consist of radiofrequent ther-motherapy, laser-assisted uvuloplasty, uvulopalatopharyngoplasty (UPPP), with or without tonsillectomy;
3) while in retrolingual obstruction surgical options are radiofrequency of the tongue base or hyoid sus-pension. In case of severe OSAS and multilevel obstruction, multilevel surgery in one tempo is increasingly performed.

Study burden and risks

Patients will visit the ENT department of the St Lucas Andreas hospital at least 3 times within the 6 month follow up. Blood will be drawn, an ECG will be performed and 24 hour blood pressure will be recorded 3 times within the 6 month follow up (0, 3 and 6 months).
Physical and psychological discomfort associated with above mentioned investigations include: painful elbow because of the venapuncture and exercise limitation because of the 24 hour blood pressure monitoring.
As far as we know, these investigations aren't of any risk to the patient.

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

Epsworth Sleepiness Scale (ESS) >9
Apnea Hypopnea Index(AHI) * 15

Exclusion criteria

Patients with an AHI<15 or ESS<10 or who suffer from predominant central sleep apnea or have contraindications for surgery will be excluded. Patients in whom relevant cardiovascular medication (lipid lowering drugs, ACE-/AT-1-inhibitors, ß-blocking agents, diuretics, calcium antagonists, nitrates, oral anti-diabetics and insulin therapy) is altered or started during follow-up will be excluded. Patients in whom OSAS surgery was not successful will be excluded. Patients having a systolic blood pressure>180mm Hg, total cholesterol (TC)>8mmol/l, TC/HDL ratio>8 or an abnormal ECG will be consulted by a cardiologist.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-04-2007
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL16172.029.07