Postoperative oxygenation pattern in patients with obstructive sleep apnea - a pilot study

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to study postoperative oxygenation patterns in patients with OSA during the first three postoperative nights and 6 weeks after operation. The results of these observations will be compared to other patients groups with known respiratory compromise...

Ethical review	Approved WMO
Status	Pending
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Observational non invasive

Summary

ID

NL-OMON31872

Source
ToetsingOnline

Brief title
Postop Saturation in OSA

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
obstructive sleep apnea

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Obstructive, Oximetry, Postoperative Complications, Sleep Apnea, Sleep Apnea Syndromes

Outcome measures

Primary outcome

Deoxygenated time in night 1-3, number of rapid deoxygenation intervals

(indicating obstruction) in the same period

Secondary outcome

Reported respiratory and cardiovascular complications

Study description

Background summary

Patients with obstructive sleep apnea (OSA) are frequently admitted to an ward where monitoring of the patients is possible (PACU, medium care unit), typically if postoperatively opioids are used to combat pain. This policy is debatable as (a part of) the apneuic intervals occur during REM sleep, which is usually absent during the first postoperative night. In the mean while REM can occur more frequently in the following night, which could concur with an increased incidence of apneuic periods.

Study objective

to study postoperative oxygenation patterns in patients with OSA during the first three postoperative nights and 6 weeks after operation. The results of these observations will be compared to other patients groups with known respiratory compromise and a control group.

Study design

open, observational study that includes patients in the order that they appear. Each study arm will be closed if 30 completely studied patients have been included.

Study burden and risks

The burden and risks of the study is minimal since the recorder is a small wrist worn device, which runs on batteries and does not immobilize the patient. The device is worn during the night. There are no known additional risks of wearing the device.

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

1. patient with proven or suspected obstructive sleep apnea
2. obese patients with BMI > 30
3. patients undergoing carotic body resection
4. healthy patients undergoing superficial surgery

Exclusion criteria

1. patients not able to give informed consent
2. patients undergoing unplanned surgery

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2008
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL23157.058.08