

# 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...

|                              |   |
|------------------------------|---|
| <b>Ethical review</b>        | Approved WMO  |
| <b>Status</b>                | Pending   |
| <b>Health condition type</b> | Upper respiratory tract disorders (excl infections) |
| <b>Study type</b>            | 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 apneic 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 apneic 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

### Public

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### Scientific

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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 carotid 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 |