PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Prospective, randomized comparison of two standard anesthesia regimens for patients with sleep apnea

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

**The sleep apnea syndrome describes a breathing disorder during sleep in which recurrent reduction (hypopnea) or cessation of breathing (apnea) can be observed. The differential effects of certain anesthesia regimens on patients with sleep apnea are not fully investigated and subject of the present study.
Patients with known or suspected sleep apnea scheduled for elective surgery are included in this study. We measure heart frequency, oxygen saturation, breathing and sleep states in the respective pre- and postoperative nights. The patients are randomly assigned to one of two standard anesthesia regimens. As far as we know now no advantage or disadvantage will be created for any patient by the assignment to either of the two regimens.
The goal of the study is to explore the influence of the two standard anesthesia regimens on patients with sleep apnea and to investigate, if one anesthesia regimen is superior to the other in this patients.**

Brief Summary in Scientific Language

Patients with sleep apnea syndrome are prone to postoperative complications, nonetheless to date the optimal anesthesia regimen for such patients is unknown. The goal of the present study is to determine a treatment pathway for patients with known or suspected sleep apnea syndrome in the preoperative phase. For that purpose we compare two established anesthesia regimens (Sevoflurane/Remifentanil vs Propofol/Remifentanil) and their influence on the Apnea-Hypopnea-Index and the desaturation index in the first postoperative night.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00005824**
- Date of Registration in DRKS: **2014/03/12**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **06-3228 , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

Secondary IDs

Health condition or Problem studied

- ICD10: **G47.3 - Sleep apnoea**

Interventions/Observational Groups

- Arm 1: **Induction of anesthesia in both groups:**
  - Etomidat 0,3 mg/kg
  - Rocuronium 0,6 mg/kg
  - Remifentanil 60 µg/kg/h

  Arm 1:

  Maintenance of anesthesia:
  - 1,5 mg/kg Propofol as loading dose, followed by 4-6 mg/kg/h
  - 12 µg/kg/h Remifentanil
- Arm 2: **Induction of anesthesia in both groups:**
  - Etomidat 0,3 mg/kg
  - Rocuronium 0,6 mg/kg
  - Remifentanil 60 µg/kg/h

  Arm 2:

  Maintenance of anesthesia:
  - 1 MAC Sevoflurane
  - 12 µg/kg/h Remifentanil

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Changes in the Apnea-Hypopnea-Index post- vs preoperative measured by polysomnography in comparison of the two anesthesia regimen.

Secondary Outcome

Changes in the desaturation index post- vs preoperative measured by polysomnography in comparison of the two anesthesia regimen.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Essen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/08/05**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
-

Gender: **Both, male and female**

Minimum Age: **18 Years**

- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients with known or suspected sleep apnea syndrome (STOP-Score >= 2), scheduled for elective surgery.

Exclusion criteria

pregnancy, pre-existing CPAP therapy, planned intranasal or intraoral surgery, patient refusal

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/12/13**

Trial Publications, Results and other documents

- Abstract **Perioperative incidence of airway obstructive and hypoxemic events in patients with confirmed or suspected sleep apnea - a prospective, randomized pilot study comparing propofol/remifentanil and sevoflurane/remifentanil anesthesia.**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*