

Safety of perioperative patients with obstructive sleep apnoea

Submission date 22/10/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/01/2008	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
EA1/016/06

Study information

Scientific Title

Acronym
OSAS

Study objectives

Polysomnographic parameters in patients with obstructive sleep apnoea are influenced by the type of surgery and the type of anaesthesia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Charité - Berlin Medical University Ethics Committee on the 18th May 2006 (ref: EA1/016/06).

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obstructive sleep apnoea

Interventions

Group 1: 20 patients with surgery with general anaesthesia

Group 2: 20 patients with surgery with regional anaesthesia

Group 3: 20 patients with surgery on the upper airway with general anaesthesia

Randomisation of participants will be carried out between groups 1 and 2. There is no randomisation in group 3.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Apnoea-hypopnoea index, based on the following:

1. Continuous polysomnographic measurement. This will be carried out at the following timepoints:

1.1. The night before surgery from 23:00 pm to 7:00 am

1.2. For 2 hours in the recovery room after extubation

1.3. After returning from the recovery room to the ward, until 7:00 am next day

2. The patients will be asked to rate the intensity/recreative power of the night sleep on a scale, from 1 (not recreative) to 5 (very recreative) the first and second morning 7:00 am

Key secondary outcome(s)

1. Patient satisfaction, based on the following:

1.1. The patients will be asked to rate his contentedness with the anaesthesia on a scale, from 1 (very content) to 5 (not content) the next morning after surgery

1.2. The patients will be asked to rate the pain on a scale from 0 (no pain) to 10 (strongest pain)

at the following timepoints:

- 1.2.1. At the beginning of the anaesthesia
- 1.2.2. Immediately after extubation
- 1.2.3. After the first hour in the recovery room
- 1.2.4. After the second hour in the recovery room
- 1.2.5. Next morning after surgery
2. Heart rate and blood pressure, measured as part of the continuous polysomnographic measurement (see primary outcome measures)
3. Circulating mediators
4. Validity of screening

Completion date

31/12/2008

Eligibility

Key inclusion criteria

1. Obstructive sleep apnoea (the Epworth Sleepiness Scale [ESS] score greater than 9)
2. Elective surgery with either general or regional anaesthesia, or airway surgery
3. Aged greater than 18 years, either sex
4. American Society of Anaesthesiologists (ASA) classification I - III

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Significant cardiovascular or pulmonary disease
2. Significant liver or renal disease
3. Significant psychiatric disease rendering the subject unable to participate in the trial
4. Drug dependency
5. Chronic opioid therapy
6. Chronic BiPAP (Bi-level Positive Airway Pressure) ventilator therapy

Date of first enrolment

01/07/2006

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Germany

Study participating centre

Chariteplatz 1

Berlin

Germany

10117

Sponsor information

Organisation

Charite - University Medicine Berlin (Charite - Universitaetsmedizin Berlin) (Germany)

ROR

<https://ror.org/001w7jn25>

Funder(s)

Funder type

University/education

Funder Name

Charite - University Medicine Berlin (Charite - Universitaetsmedizin Berlin) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration