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Safety of perioperative patients with obstructive sleep apnoea

Submission date	Recruitment status	[ ] Prospectively registered
22/10/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/01/2008	Nervous System Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Obstructive sleep aponea

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 measure
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

Secondary outcome measures
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

Overall study start date
01/07/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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)

Sponsor details
Chariteplatz 1
Berlin
Germany
10117

Sponsor type
University/education

Website
http://www.charite.de

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration