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Cognitive function after sevoflurane- versus propofol-based anaesthesia for on-pump cardiac surgery

Submission date 18/02/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/03/2010	**Overall study status** Completed	
Last Edited 15/03/2010	**Condition category** Surgery	

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
Cogdys1

Study information

Scientific Title
Cognitive function after sevoflurane- versus propofol-based anaesthesia for on-pump cardiac surgery: a randomised controlled trial

Acronym
C01

Study objectives
The present study was designed to contribute to the question, whether a sevoflurane-based anesthesia concept improves cognitive outcomes in patients undergoing cardiac surgery with cardiopulmonary bypass in comparison to a propofol-based total intravenous anaesthesia.

The secondary objective was to determine if the treatment with sevoflurane in comparison to a propofol-based anaesthesia leads to differences in regional cerebral oxygenation measured with near-infrared spectroscopy (NIRS). Further, differences in the relationship between regional cerebral desaturation and cognitive decline, and differences between anaesthetic regimens regarding relevant clinical outcome-parameters should be investigated.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Committee of the University of Luebeck approved in February 2006 (ref: 05-139)

Study design
Randomised controlled investigator-blinded 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
Cardiac surgery, cognitive dysfunction

Interventions

Anaesthesia protocol 1: intravenous group (PROP):
Induction: etomidate 0.2 - 0.3 mg/kg, sufentanil 1 µg/kg, pancuronium 0.07 - 0.1 mg/kg
Maintenance: remifentanil 0.2 - 0.25 µg/kg/min, propofol 3 - 5 mg/kg/h achieving a bispectral index (BIS) of 40 - 50.

Anaesthesia protocol 2: volatile group (SEVO):
Induction: etomidate 0.2 - 0.3 mg/kg, sufentanil 1 µg/kg, pancuronium 0.07 - 0.1 mg/kg
Maintenance: sevoflurane 0.6 - 1.5 MAC, remifentanil 0.2 - 0.25 µg/kg/min achieving a BIS of 40 - 50
During cardiopulmonary bypass: remifentanil 0.2 - 0.25 µg/kg/min, propofol 3 - 5 mg/kg/h achieving a BIS of 40 - 50

The treatment was carried out throughout the surgical procedure. The follow up was conducted 2, 4 and 6 days after surgery. The total length of hospital stay was recorded post hoc. No follow up after hospital discharge was performed.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sevoflurane, etomidate, sufentanil, pancuronium, remifentanil, propofol

Primary outcome measure
Cognitive function measured with the abbreviated mental-test (AMT), stroop-test, trail-making-test (TMT), word-lists (WL), and mood-assessment-tests on day 2, 4 and 6 after cardiac surgery

Secondary outcome measures
1. Markers of myocardial, cerebral and renal damage (creatine kinase [CK]/creatine kinase myocardial bands [CK-MB], troponin, high sensitivity troponin [hsTroponin], N-terminal prohormone brain natriuretic peptide [NT-proBNP], neurone specific enolase [NSE], beta-subunit of S100 protein [S100beta], neutrophil gelatinase-associated lipocalin [NGAL], cystatin C [CysC], creatinine), measured 2, 4 and 6 days after surgery
2. Clinical outcome concerning brain, kidney and heart, recorded 6 days after surgery

Overall study start date
01/09/2006

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. Aged between 18 and 85 years, either sex
2. Elective or urgent cardiac surgery with cardiopulmonary bypass
3. American Society of Anaesthesiologists (ASA) grade I to IV

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
n = 64 for each group, total N = 128

Key exclusion criteria
1. Overt neurological diseases or dementia
2. Significant stenosis of the carotid arteries
3. Pregnancy
4. Disposition for malignant hyperthermia
5. Use of monoamine oxidase-inhibitors
6. Insufficient knowledge of the German language
7. Emergency indication

Date of first enrolment
01/09/2006

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
Germany

Study participating centre
Department of Anesthesiology
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Sponsor information

Organisation
University of Luebeck (Germany)

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Sponsor type
University/education

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http://www.mu-luebeck.de/

ROR
https://ror.org/00t3r8h32

Funder(s)

Funder type
University/education

Funder Name
University of Luebeck (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