

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

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Registration date 15/03/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/03/2010	Condition category Surgery	<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

Contact name

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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 (creatinine kinase [CK]/creatinine 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

Luebeck

Germany

23538

Sponsor information

Organisation

University of Luebeck (Germany)

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Sponsor type

University/education

Website

<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