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Assessment of cerebral oxygen supply-demand balance by near-infrared spectroscopy during induction of anesthesia in patients undergoing coronary artery bypass graft surgery: Comparison of midazolam with propofol

Submission date
11/02/2008

Recruitment status
No longer recruiting

Registration date
27/02/2008

Overall study status
Completed

Last Edited
16/08/2011

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
N/A

Study information

Scientific Title

Study objectives
Near-InfraRed Spectroscopy (NIRS) continuously measures regional cerebral oxygen saturation (rSO2) noninvasively and has been shown to detect even small changes in cerebral oxygen supply-demand balance elicited by etomidate. Propofol and sufentanil have been well studied in human subjects in terms of cerebral oxygen supply-demand balance with both agents decreasing cerebral blood flow and metabolism to a similar degree. Although widely used, only the effect of midazolam on cerebral blood flow has been studied in humans and evidence is lacking about its effect on cerebral metabolic rate. By far, no comprehensive data exist regarding the influence of midazolam and hemodynamic changes on rSO2 scores during the induction period. We therefore evaluated the effect of midazolam on cerebral oxygen supply-demand balance by continuous monitoring of rSO2 in a prospective, randomized and controlled trial with concomitant monitoring of hemodynamic variables including cardiac index and mixed venous oxygen saturation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (IRB) of Yonsei University Health System, Seoul, Korea. Date of approval: 27 October 2006 (ref: 4-2006-0155)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Coronary artery bypass graft surgery

Interventions
Upon arrival at the operating room, standard monitoring devices were applied and a radial artery catheter was inserted under local anaesthesia for continuous blood pressure monitoring. Also, a pulmonary artery catheter (Swan-Ganz CCOmbo, CCO/SvO2, Edwards Lifesciences LLC, USA) was inserted via the right internal jugular vein under local anesthesia for continuous measurement of Cardiac Index (CI) and mixed-venous oxygen saturation (SvO2). Bispectral index (Bispectral Index Scale; BIS) (A-2000TM, Aspect Medical Systems, USA) and rSO2 (INVOS 5100TM, Somanetics, USA) were continuously monitored with both sensors applied to the forehead of the patients.

Hemodynamic variables, BIS and rSO2 scores were recorded at the following time points:
1. Before induction while patients were breathing room air (T1, baseline)
2. After pre-oxygenation with 100% oxygen for at least 3 min through tight-fitting anesthetic mask (T2)
3. Three minutes after administration of either midazolam 0.05 mg/kg or propofol 1 mg/kg according to randomization (T3)
4. Three minutes after completion of administration of sufentanil 1.52 µg/kg (T4)
5. Five 5 min after tracheal intubation (T5)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
midazolam and propofol

Primary outcome measure
Regional cerebral oxygen saturation measured by near infrared spectroscopy

Secondary outcome measures
Hemodynamic variables including the following:
1. Cardiac index (CI)
2. Mixed venous oxygen saturation
3. Mean arterial pressure
4. Central venous pressure

Overall study start date
31/08/2006

Completion date
31/03/2007

Eligibility

Key inclusion criteria

Adult patients admitted to the Yonsei University Health System scheduled for isolated off-pump coronary artery bypass graft surgery between August 2006 and March 2007.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Patients undergoing emergent surgery
2. Pre-existing neurologic disease
3. Lung parenchymal disease
4. New York Heart Association (NYHA) functional class >= 3
5. Left ventricular ejection fraction <40%
6. Unstable angina and recent myocardial infarction within 1 month
7. Patients who had significant luminal narrowing of either carotid and/or vertebral arteries on preoperative angiography

Date of first enrolment
31/08/2006

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
Korea, South

Study participating centre
Department of Anaesthesiology and Pain Medicine
Seoul
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Sponsor information

Organisation
Yonsei University, College of Medicine (Korea, South)

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Sponsor type
University/education

Website
http://medicine.yonsei.ac.kr/en

ROR
https://ror.org/01wjejq96

Funder(s)

Funder type
University/education

Funder Name
Yonsei University, College of Medicine (Korea, South)

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