

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	Recruitment status	<input type="checkbox"/> Prospectively registered
11/02/2008	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
27/02/2008	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
16/08/2011	Circulatory System	<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

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

Study type(s)

Treatment

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 anaesthesia 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(s)

Regional cerebral oxygen saturation measured by near infrared spectroscopy

Key secondary outcome(s)

Hemodynamic variables including the following:

1. Cardiac index (CI)
2. Mixed venous oxygen saturation
3. Mean arterial pressure
4. Central venous pressure

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Korea, South

120-752

Sponsor information

Organisation

Yonsei University, College of Medicine (Korea, South)

ROR

<https://ror.org/01wjej96>

Funder(s)

Funder type

University/education

Funder Name

Yonsei University, College of Medicine (Korea, South)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration