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Bispectral index guided induction of general anaesthesia in patients scheduled for major abdominal surgery: propofol versus etomidate

Submission date 22/01/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/03/2011	**Overall study status** Completed	
Last Edited 07/09/2011	**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
N/A

Study information

Scientific Title
Bispectral index guided induction of general anaesthesia in patients scheduled for major abdominal surgery: single-centre double blinded crossover randomised controlled trial of propofol versus etomidate

Acronym
BIS PROPETO

Study objectives
We will compare the induction of general anaesthesia with etomidate and propofol both titrated to the same bispectral index value:
1. Can we reach a decrease of the needed dose and an alleviation of the negative haemodynamic effects of the induction agent by titrating it to the needed anaesthesia depth?
2. Which induction agent has more negative haemodynamic effects after intubation in terms of hypotension and bradycardia?
3. Which induction agent is accompanied by more tachycardia and hypertension during laryngoscopy and intubation?
4. Is the time of titration of both induction agents to the appropriate anaesthesia depth comparable?
5. Are the haemodynamic effects of both induction agents comparable?

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Medical Ethics Committee approved on the 28th September 2010 (ref. 117/09/10)

Study design
Single-centre double blinded crossover 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
General anaesthesia in major abdominal surgery

Interventions
The study will compare the haemodynamic effects of two intravenous induction agents which will be titrated to the appropriate anaesthesia depth monitored with bispectral index monitor.

Two groups of patients are scheduled for major abdominal surgery. The only difference between the groups is the random chosen induction agent for general anaesthesia: propofol or etomidate. With a constant rate the induction agent is titrated with a perfusor to a bispectral index of 60, then the infusion is stopped. After 1 minute the patient is intubated and ventilated with a mixture of oxygen and air (40:60) and 1% sevoflurane.

Bispectral index, heart rate (HR), oxygen saturation, invasive measured mean arterial pressure (MAP) and cardiac output are measured. The values are written down every minute from 2 minutes before the beginning of the anaesthesia induction until 10 minutes after intubation. A BIS monitor is used to monitor the bispectral index. The haemodynamic parameters are measured with a LiDCOrapid monitor. The time from the beginning of the infusion to the bispectral index 60 and from the beginning of the infusion to the disappearance of the eyelash reflex is also measured. At the end of the follow-up the induction agent is identified and a note of the dose of the induction agent is made.

There is a rescue protocol for excessive hypotension (mean arterial pressure [MAP] less than 55 mmHg), hypertension (MAP greater than 100 mmHg), bradycardia (heart rate [HR] less than 40 /min), tachycardia (HR greater than 90/min) or arrhythmia. The rescue drugs are:
1. Ephedrine 5 mg, phenylephrine 50 µg or atropine 0.3 mg in case of hypotension or bradycardia
2. Fentanyl 0.01 mg/kg, nitroglycerine 10 - 100 µg/min or esmolol 25 - 200 µg/kg/min in case of hypertension or tachycardia or arrhythmia

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Propofol, etomidate

Primary outcome measure
Measured from the start of induction till 10 minutes after intubation:
1. Middle arterial pressure
2. Pulse
3. Cardiac output
4. Bispectral index
5. Oxygen saturation of haemoglobin

Secondary outcome measures
1. Dose of each induction agent
2. Time from start of anaesthesia induction to laryngoscopy and intubation
3. Dose of each needed rescue drug

Overall study start date
01/11/2010

Completion date
01/05/2011

Eligibility

Key inclusion criteria
1. Aged over 40 years, either sex
2. American Society of Anasthesiologists (ASA) grade III
3. Scheduled for major abdominal surgery (large bowel resection, stomach resection, liver resection, Whipple resection)

All patients will get an epidural catheter in the lower half of the thoracic spine.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Alcohol-abuse
2. Drug abuse
3. Chronic use of benzodiazepines, opioides or other psychotrophic substances
4. Body mass index greater than 30
5. Anticipated difficult intubation (Mallampati 3 and 4)
6. Kidney disease (serum kreatinin greater than 120 mmol/l)
7. Manifest liver disease
8. Alzheimer disease
9. Epilepsy
10. Left ventricle ejection fraction less than 30%
11. Haemodynamic important heart valve disease
12. Pacemaker

Date of first enrolment
01/11/2010

Date of final enrolment
01/05/2011

Locations

Countries of recruitment
Slovenia

Study participating centre
Ljubljanska ulica 5
Maribor
Slovenia
2000

Sponsor information

Organisation
University Medical Centre Maribor (Slovenia)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02rjj7s91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Maribor (Slovenia) - Department of Anaesthesiology, Intensive Care Therapy and Pain Management

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