

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/09/2011	Condition category Surgery	<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
Mrs Andreja Möller Petrun

Contact details
Ljubljanska ulica 5
Maribor
Slovenia
2000
andreja@moellerpetrun.net

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 Anesthesiologists (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, opioids or other psychotropic 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

Department of Anaesthesiology
Intensive Care Therapy and Pain Management
Ljubljanska ulica 5
Maribor
Slovenia
2000
mirt.kamenik@ukc-mb.si

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