ISRCTN68690518 https://doi.org/10.1186/ISRCTN68690518

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

| | | |
|---|---|---|
| **Submission date**<br>22/01/2011 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>01/03/2011 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>07/09/2011 | **Condition category**<br>Surgery | [_] Individual participant data<br>[_] 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

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)
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

### Key secondary outcome(s))
1. Dose of each induction agent
2. Time from start of anaesthesia induction to laryngoscopy and intubation
3. Dose of each needed rescue drug

### 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

### Healthy volunteers allowed

No

### Age group
Adult

### Sex
All

### 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)

### 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

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |