ISRCTN81365561 https://doi.org/10.1186/ISRCTN81365561

Haemodynamic stability during anaesthesia induction with propofol the impact of phenylephrine

Submission date	Recruitment status	[_] Prospectively registered
07/06/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/07/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/05/2020	Surgery	

Plain English summary of protocol

Background and study aims
Propofol is a drug that is widely used to anaesthetize a person before they have an operation. One of the effects of propofol is a drop in blood pressure. Other drugs, called vasopressors, have to then be given to the patient in order to raise the blood pressure to a more normal level. In this study, we will assess how well a continually administrated dose of a vasopressor (phenylephrine), given when the patient is being put under a general anaesthetic with propofol, is at maintaining a more stable blood pressure.

Who can participate?
Adult patients with abdominal cancers about to have high-risk abdominal surgery.

What does the study involve?
Patients are randomly allocated into one of two groups. One group are given a continuous dose of phenylephrine while being put under a general anaesthetic with propofol. The other group are given a saline solution instead. The blood pressure of both groups of patients are measured during the start (induction) of anaesthesia and compared.

What are the possible benefits and risks of participating?
All patients are closely monitored, including continually measuring both their blood pressure and heart rate, throughout the procedure. Any possible increase or decrease in blood pressure compared to the norm will be immediately identified and treated. Therefore patients are not exposed to any additional risk.

Where is the study run from?
The Maribor University Clinical Centre (Slovenia)

When is study starting and how long is it expected to run for?
November 2013 to January 2015

Who is funding the study?
The Maribor University Clinical Centre (Slovenia)

Who is the main contact?
Professor Mirt Kamenik
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IRP-2013/02-06

Study information

Scientific Title
The impact of phenylephrine infusion on haemodynamic stability during bispectral index (BIS) guided anaesthesia induction with propofol a double-blind randomised controlled trial

Acronym
BIS PROPphen

Study objectives
We will compare the induction of general anaesthesia with propofol and propofol combined with phenylephrine both titrated to the same bispectral index value. We expect less hypotension and cardiac output decrease during and after the induction of anaesthesia with the use of the combination of propofol and phenylephrine. We are also interested which impact does phenylephrine have on other haemodynamic parameters during and after induction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Medical Ethics Committee;10/10/2013; ref. 229/09/13

Study design
Single-centre double-blinded prospective randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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
Cardiovascular disease and abdominal cancer surgery

Interventions
We will study the haemodynamic effects of intravenous anaesthesia induction with propofol titrated to the appropriate anaesthesia depth monitored with spectral index monitor. During induction the patients will receive a continuous infusion of either phenylephrine or saline in a double blind randomized fashion. Hypotension (<55 mmHg) will be managed with additional phenylephrine. Hypertension (>100 mmHg) will be managed with the stop of infusion, additional, fentanyl and nitro-
glycerine. Tachycardia (>90/min) will be managed with fentanyl and esmolol. Bradycardia (<40 /min) will be managed with atropine.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Mean arterial pressure
2. Cardiac output
3. Systemic vascular resistance
All outcomes will be measured by the LIDCCORapid monitor for measuring cardiac output. The new generation of LIDCCORapid monitor enables also the measurement of the depth of anaesthesia with the BIS monitor. The measurements will be done at baseline and for 20 minutes during the induction of anaesthesia. The LIDCCORapid monitor enables automatic online collection of the data which will be averaged over one minute intervals for the period of

induction. The averaged data for both groups of the results will be presented for baseline values, the values immediately before laryngoscopy and intubation, 2 minutes after intubation and then in 3 minute intervals till the end of measurements.

Secondary outcome measures
1. Heart rate
2. Stroke volume
3. Bispectral index
4. Oxygen saturation
5. Dose of propofol
6. Time from start of anaesthesia induction to laryngoscopy and intubation
7. Dose of rescue drugs needed

The other secondary outcome measures: the dose of propofol during induction of anaesthesia, the time to laryngoscopy and intubation, the frequency of rescue medication used and the dose of rescue medication given is registered during the study for each study subject and the data are collected on our protocol sheet.

Overall study start date
01/11/2013

Completion date
01/01/2015

Eligibility

Key inclusion criteria
ASA II-III patients scheduled for major abdominal surgery (large bowel resection, stomach resection, liver resection, Whipple resection) and major urologic surgery (bladder resection, prostatic cancer).

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Total final enrolment
40

Key exclusion criteria
1. Alcohol-abuse
2. Drug abuse
3. Chronic use of benzodiazepines, opioids or other psychotropic substances
4. Body mass index > 30

5. Anticipated difficult intubation (Mallampati 3 and 4)
6. Kidney disease (serum creatinine > 120 mmol/l)
7. Manifest liver disease
8. Alzheimer disease
9. Epilepsy

Date of first enrolment
01/11/2013

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Slovenia

Study participating centre
V zatiju 20
Bresternica
Slovenia
2354

Sponsor information

Organisation
Maribor University Clinical Centre (Slovenia)

Sponsor details
Ljubljanska 5
Maribor
Slovenia
2000

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02rjj7s91

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Maribor University Clinical Centre (Slovenia)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2018	29/05/2020	Yes	No