

Hemodynamic stability during anesthesia induction with ketofol mixture – identifying optimal ratio

Submission date 10/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/08/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/08/2017	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Surgery has to be as safe as possible and patients are prepared to be in the best condition possible before elective surgery. The main role of anesthesiologist during surgery is managing and treating changes in patient's critical life functions (such as breathing, heart rate, blood pressure etc) by giving them a medication called anesthesia. Patients are required to be in their medically induced coma temporary coma before the surgeon can begin surgery, as well it is helpful to be in the coma while the breathing tube is placed in patients throats as this is painful and unpleasant. Then, patients require their breathing airway to be secured by a breathing tube placed in the throat, which is painful and unpleasant. Therefore, it is important that patients are placed into their coma for the surgery quickly and safely. Different medications are used during surgery, and one of the most common ones used is called propofol. Another commonly used medication is called esketamine. Sometimes these are mixed together for outpatient procedure situations. The mixture is known as "ketofol". Ketofol is not used for the induction of coma for general anesthesia but could have the potential to. The aim of this study is to see if undergoing anesthesia with ketofol is able to provide stable critical life function parameters than propofol and to examine different mixtures of ketofol in order to help establish a standardized formula of what should be in the mixture.

Who can participate?

Healthy adults aged between 18 and 80 years old with no severe chronic illness undergoing elective surgery requiring general anesthesia.

What does the study involve?

Participants are randomly allocated to one of three groups. All participants undergo the surgery but receive different anaesthesia based on their allocation. Those in the first group receive ketofol with propofol:esketamin ratio of 1:1. Those in the second group receive ketofol with propofol:esketamin ratio 2:1. Those in the last group receive propofol. Surgeries are done to the standard level of care. Participants have their vital signs, hemodynamic status (measuring of heart function) and coma depth monitored throughout the surgery.

What are the possible benefits and risks of participating?
There are no notable benefits or risks involved with participating.

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

When is the study starting and how long is it expected to run for?
January 2017 to December 2018

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

Who is the main contact?
Dr Domen Kogler
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
KME 39/08/16

Study information

Scientific Title
Hemodynamic stability during anesthesia induction with propofol/esketamine (ketofol) mixture – identifying optimal ratio

Study objectives
The aim of this study is to compare the hemodynamic stability during anesthesia induction with ketofol in different concentration mixtures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Republic of Slovenia National Medical Ethics Committee - NMEC, 25/09/2016, ref: 0120-395 /2016-2; KME 39/08/16

Study design

Randomised double blind controlled parallel trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Elective surgery with orotracheal intubation

Interventions

Participants undergoing elective surgery are randomly allocated to one of three groups. Randomisation is done by an independent person using a draw. The following groups are:

Group K1: Participants in this group receive an anesthetic mixture of 10 ml 1% propofol and 4 ml 2,5% esketamine

Group K2: Participants in this group receive an anesthetic mixture mixture of 10 ml 1% propofl, 2 ml 2,5% esketamine and 2 ml 0,9% NaCl solution

Group P: Participants in this group receive an anesthetic mixture of 10 ml 1% propofol and 4 ml 0,9% NaCl solution (control)

All participants are premedicated with midazolam one hour before surgery. All patients follow the same protocol for first 16 minutes, the only variable is anaesthetic mixture. Anaesthesia induction starts at time 0 when patient gets 0,25 mcg/kg of sufentanyl (concentration 5 mcg/ml, rounded to nearest ml). At 120 seconds all participants receive 5 ml bolus of anaesthetic mixture following titration with 1 ml until clinical effect (lose of palpebral efect). Then 0,6 mg/kg (concentration 10mg/ml, rounded to nearest ml) is administered to patient following another 2ml of anaesthetic mixture. Between minute 4 and 5 (time 240 s to 300 s) the patient is intubated and then mechanically ventilated, maintaining anesthesia with sevoflurane 1,0-1,5 vol%.

Dosing is titrated to clinical effect (lose of palpebral effect) with blinded recording of Bispectral index.

Total duration of treatment is one hour before surgery (premedication) untill one hour after surgery (recovery from anaesthesia) for all treatment arms (sturdy groups). Duration of data collection study is first 16 minutes after application of sufentanyl (start of anaesthesia induction). Follow up is the same for all treatments arms and ends one hour after surgery (recovery from anaesthesia).

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Propofol, esketamine

Primary outcome(s)

1. Cardiac output is measured noninvasively using transthoracic electric bioimpedance every minute for first 16 minutes after induction of anesthesia
2. Blood pressure is measured noninvasively using arm cuffs every 2 minutes for first 16 minutes after induction of anesthesia
3. Heart rate is measured by ECG every minute for first 16 minutes after induction of anesthesia

Key secondary outcome(s)

1. Bispectral index (BIS) (depth of sedation or anaesthesia) is monitored with 15 seconds sampling using forehead electrodes every minute for first 16 minutes after induction of anesthesia.
2. Dose titrated to clinical effect (loss of palpebral effect)

Completion date

31/12/2018

Eligibility

Key inclusion criteria

1. Aged 18-80 years
2. ASA Physical Status I or II
3. Elective surgery with orotracheal intubation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

Key exclusion criteria

1. Allergy or sensitivity to any medication used in trial
2. Alcohol or drug abuse
3. Chronical use of benzodiazepins, opiats or psychothrophic medication
4. Body mass index higher than 35 or lower than 15
5. Anticipated difficult intubation (Mallampati III or IV)
6. Untreated arterial hypertension
7. Patients with Alzheimers, epilepsy or psychosis

Date of first enrolment

01/08/2017

Date of final enrolment

30/06/2018

Locations

Countries of recruitment

Slovenia

Study participating centre

University Clinical Centre Maribor

Ljubljanska ulica 5

Maribor

Slovenia

2000

Sponsor information

Organisation

University Clinical Centre Maribor

ROR

<https://ror.org/02rjj7s91>

Funder(s)

Funder type

University/education

Funder Name

University Clinical Centre Maribor

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Domen Kogler at domen.kogler@gmail.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			02/08/2017	No	Yes