

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

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<b>Registration date</b> 02/08/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/08/2017	<b>Condition category</b> 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

**Contact name**  
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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](mailto:domen.kogler@gmail.com)

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			02/08/2017	No	Yes