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

Submission date
10/06/2017

Recruitment status
No longer recruiting

Registration date
02/08/2017

Overall study status
Completed

Last Edited
02/08/2017

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 profol:esketamin ratio of 1:1. Those in the second group receive ketofol with profol: 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, hemodinamic 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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 measure
1. Cardiac output is measured noninvasively using transthoracal 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

Secondary outcome measures
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)

Overall study start date
01/01/2017

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
100

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 psyhothrophic 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

Sponsor details
Ljubljanska ulica 5
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Slovenia
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Sponsor type
Hospital/treatment centre

Website
http://www.ukc-mb.si/en/

ROR
https://ror.org/02rjj7s91

Funder(s)

Funder type
University/education

Funder Name
University Clinical Centre Maribor

Results and Publications

Publication and dissemination plan
Planned publication in a impact peer reviewed journal.

Intention to publish date
10/10/2019

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