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# Propofol sedation during diagnostic colonoscopy

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 01/09/2015 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 14/09/2015 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 27/04/2018 | Other | |

## Plain English summary of protocol

Background and study aims
A colonoscopy is an important procedure, in which a narrow, flexible, telescopic camera is inserted into the back passage to look at the lining of the large bowel. It is often an unpleasant, uncomfortable and painful procedure; more patients are therefore requesting deep sedation throughout, despite the risks associated with anaesthesia. Propofol is a medication which is commonly used for sedation during colonoscopies, as it starts working and wears off very quickly. It has been found however, that propofol can have harmful effects on breathing and the heart. In order to lower risk for patients, balanced propofol sedation (BSP) may be used, in which small doses of sedatives and pain killers are given at the same time so that a lower dose of propofol can be given. One of the most advanced ways of sedating patients in this way is by using target-controlled infusion (TCI). This is where the amount that the propofol given to the patient is adjusted automatically by a pump controlled by a computer. This ensures that the patient does not receive too little or too much of the drug to maintain their level of sedation. The aim of this study is to compare the safety for patients, and the comfort of the endoscopist performing the procedure, when propofol is given automatically (TCI) or manually.

Who can participate?
Adults scheduled for a diagnostic outpatient colonoscopy with deep sedation.

What does the study involve?
Patients are randomly allocated into one of two groups. All patients receive propofol, as well as small doses of midazolam (a sedative) and fentanyl (a strong pain killer). For patients in the first group, the drugs are controlled manually by an anesthesiologist, and for those in the second group, the drugs are given using TCI. Throughout the study, the vital signs (i.e. heart rate, blood pressure and breathing) of patients are monitored so that any adverse effects of the drugs can be recorded. At the end of the study, the endoscopists who performed the procedure complete questionnaires to evaluate their comfort during the procedure (i.e. how difficult it was to perform, how well the sedation worked).

What are the possible benefits and risks of participating?
There are no notable benefits or risks of participating, as both methods are used in everyday practice.

Where is the study run from?
Clinical Center of Serbia (Serbia)

When is the study starting and how long is it expected to run for?
January 2013 to October 2014

Who is funding the study?
Clinical Center of Serbia (Serbia)

Who is the main contact?
Dr Vera Vucicevic

# Contact information

### Type(s)
Scientific

### Contact name
Dr Vera Vucicevic

### Contact details
Visegradska 26
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Serbia
11000

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# Study information

### Scientific Title
Manually versus target controlled infusion in balanced propofol sedation during diagnostic colonoscopy: a prospective randomized controlled trial

### Study objectives
The aim of this study is to compare safety and comfort of endoscopist in the two methods of balanced propofol sedation targeting deep sedation: propofol target-controlled infusion with manual intravenous titration technique during colonoscopy.

### Ethics approval required

Old ethics approval format

## Ethics approval(s)
Institutional Ethics Committee of the Clinical Centre of Serbia, 01/08/2012, ref: 4183/01.08.2012

## Study design
Single-centre interventional prospective randomised parallel trial

## Primary study design
Interventional

## Secondary study design
Randomised parallel trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format

## Health condition(s) or problem(s) studied
Patients undergoing a colonoscopy

## Interventions
In the endoscopy room intravenous access is obtained and each patient received 8 ml/kg/h of isotonic saline solution in the form of infusion and 100% oxygen is supplemented with a mask (6 L/min). Pre-induction medication for all patients is as follows: midazolam (Dormicum, Roche Pharma, Reinach, Switzerland 5 mg/5ml) in a bolus of 2 mg for the patients up to 70 kg, and 3 mg for those over 70 kg, and fentanyl (Fentanyl, Janssen-Cilag, Baar, Switzerland 0.05 mg/ml) in a bolus of 1ml for the patients between 50 and 60 kg, 1.5 ml for the patients between 60 and 80 kg, and 2 ml for those over 80 kg. Both drugs were administrated slowly (> 60 seconds), 2 minutes before propofol. The patients in the manual titration group (n=45) receive propofol intravenously (Diprivan, Astra-Zeneca, Stocholm, Sweden 10 mg/ml), in a bolus of 0.5 mg/kg, and then 10-20 mg are titrated every 1 to 2 minutes. The target-controlled infusion (TCI) group (n=45) receive propofol with TCI pump (Alaris PK, Cardinal Health), according to the Schnider's pharmacokinetic model, with the initial Ce of 2.5 μg/ml. This concentration is increased or decreased for 0.5-1 μg/ml until the desired level of sedation was achieved. Administration of propofol is stopped at the end of the colonoscopy.
The patients are monitored at 5-minute intervals: the heart rate is measured automatically as well as the blood oxygen saturation (SpO2) using pulse oximeter (Drager, Oxipac); systolic (SAP) and diastolic (DAP) arterial pressure are measured manually in serial manner, then mean arterial blood pressure (MAP) is calculated and respiration rate per minute is recorded (RR). The Modified Observer's Assesment of Alertness/Sedation (MOAA/S) scale (12) is used to document the patients responsiveness scores. The patients who lose response to verbal commands and eyelash reflex (MOAA/S = 2) are considered to be unconscious.

## Intervention Type
Other

### Primary outcome measure
Adverse events between the two treatment areas monitored throughout the study:
1. Mean arterial blood pressure < 60 mmHg (hypotension) or > 105 mmHg (hypertension
2. Heart rate < 45 beats/min (bradycardia) or > 115 beats/min (tachycardia)
3. Blood oxygen desaturation < 92% for longer than 30 sec (hypoxemia)
4. Number of respirations <6/min (bradypnea) or 0 (apnea)
5.Any other advenrse effects (e.g. coughing, hiccupping)

### Secondary outcome measures
After the procedure, the comfort of the endoscopist is measured using the following:
1. Assessing the difficulty of colonoscopy with 11-point (0-10) and with verbal Numerical Pain Rating Scale (NRS)
2. Difficulty of the experience on the scale, with 0 being “not difficult at all” and 10 “the most difficult experience imaginable”
3. Assessment of patients' sedation using verbal scale for the quality of sedation from 1-4 (1-excellent, 2-good, 3-fair, 4-poor)
4. Assessment of patients' comfort based on the observation of defensive reactions during colonoscopy
5. Overall satisfaction with procedure using verbal scale for comfort from 1-5 (1-excellent, 2-very good, 3-good, 4-fair, 5-poor).

### Overall study start date
01/01/2013

### Completion date
25/10/2014

## Eligibility

### Key inclusion criteria
1. Aged between 18 and 65 years old
2. Body weight from 50 to 120 kg
3. Classified to groups I (normal, healthy patient) or II (mild systemic disease) according to the American Society of Anesthesiologists
4. Scheduled for diagnostic outpatient colonoscopy with deep sedation

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
90

### Key exclusion criteria
1. Allergy to the study drugs
2. Previous problems with anesthesia or sedation
3. History of stridor snoring or sleep apnea
4. Neck abnormalites
5. Those classified to groups III or IV of Mallampati classification.

### Date of first enrolment
01/04/2013

### Date of final enrolment
25/10/2013

## Locations

### Countries of recruitment
Serbia

### Study participating centre
**Clinical Center of Serbia**
Visegradska 26
Belgrade
Serbia
11000

## Sponsor information

### Organisation
Institutional Ethics Committee of the Clinical Center of Serbia

### Sponsor details
Visegradska 26
Belgrade
Serbia
11000

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/02122at02

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Clinical Center of Serbia

# Results and Publications

### Publication and dissemination plan
Publication in one of the BioMed Central journals.

### Intention to publish date
31/12/2015

### Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/09/2016 | | Yes | No |