

The influence of the continuous administration of a stimulants (ephedrine or phenylephrine) into a vein on the stability of the blood flow through the heart and blood vessels after the local anesthetic is injected around the spinal cord in the senior adults

Submission date 15/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/09/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/11/2019	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims.

Spinal (subarachnoid) anaesthesia is an alternative to general anaesthesia (being put to sleep for surgery), which involves an injection of a local anaesthetic (numbing agent) into a space in the spine to numb the lower part of the body. Although this technique is very effective, it can lead to a drop in blood pressure and cardiac output (the amount of blood the heart pumps in one minute). Vasopressors are group of drugs that are given to patients to raise blood pressure. The most commonly used vasopressors are ephedrine and phenylephrine. When vasopressors are given, fluids (such as ringer solution) are often given at the same time to increase the amount of circulating blood in the body. Currently, there are no studies showing whether continuously delivering ephedrine and phenylephrine through a drip is an effective way of preventing decrease in blood pressure and cardiac output after spinal anaesthesia in adults or elderly patients. The aim of this study is to investigate the effects of ringer solution combined with continuous infusion of vasopressors (ephedrine or phenylephrine) blood pressure and cardiac output in surgical patients.

Who can participate?

Adult patients aged 50 years and over undergoing leg surgery.

What does the study involve?

Patients are randomly allocated into three groups. All participants receive spinal anaesthesia, which involves injection of a local anaesthetic into the subarachnoid space (space in the spine), and receive 100ml ringer solution over 30 minutes through a drip to help regulate their bodily processes. Those in the first group receive an infusion of saline (salt water) through a drip at the same time as receiving the Ringer solution. Those in the second group receive an infusion of

ephedrine through a drip. Those in the third group receive a an infusion of phenylephrine through a drip. Heart rate and blood pressure are measured using a specialised device 5 minutes before and 30 minutes after the spinal anaesthesia is given in all groups.

What are the possible benefits and risks of participating?

Patients in all groups benefit from being closely monitored with advanced circulation monitoring system. There are no notable risks involved with participating.

Where is the study run from?

University Medical Centre Maribor (Slovenia)

When is study starting and how long is it expected to run for?

July 2017 to January 2018

Who is funding the study?

University Medical Centre Maribor (Slovenia)

Who is the main contact?

Dr Miodrag Žunić

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

National Medical Ethics Committee of Slovenia number: 0120-8/2017-3, KME 21/01/17-bis

Study information

Scientific Title

The influence of the infusion of ephedrine and phenilephrine on the stability of the circulation after subarachnoidal anesthesia in senior adults

Study objectives

1. The blood pressure and the cardiac output in the elderly patients, older than 50 years, who are going to have lower extremity surgery after subarachnoidal anesthesia, is more stable if they have continuous infusion of ephedrine or phenilephrine in addition to Ringer lactate infusion in comparison with the group treating only with Ringer lactate infusion
2. Ephedrine will increase cardiac output and systemic vascular resistance, while phenilephrine will predominately increase systemic vascular resistance

Ethics approval required

Old ethics approval format

Ethics approval(s)

National Medical Ethics Committee, 26/01/2017, ref: 0120-8/2017-3, KME 21/01/17-bis

Study design

Single-centre double-blind prospective randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Subarachnoidal anesthesia

Interventions

In the operating theatre, participants are randomised to one of three groups using closed envelope randomisation.

Group 1: Participants receive 1000 ml of Ringer solution infusion in 30 minutes after subarachnoidal anesthesia. At the same time a 30 ml infusion of 0,9% NaCl via continued infusion over 30 minutes is started.

Group 2: Participants receive 1000 ml of Ringer solution infusion in 30 minutes after subarachnoidal anesthesia. At the same time a 30 ml infusion of 0,9% NaCl with 250 mcg of phenylephrine via continued infusion over 30 minutes is started.

Group 3: Participants receive 1000 ml of Ringer solution infusion in 30 minutes after subarachnoidal anesthesia. At the same time a 30 ml infusion of 0,9% NaCl with 20mg of ephedrine via continued infusion over 30 minutes is started.

Participants in all groups undergo rescue measurements in case of haemodynamic instability:

1. Hypotension (decrease of systolic aortic pressure of more than 30% of the basic measurements before subarachnoidal anesthesia, or if the value of the systolic aortic pressure is less than 90 mmHg): additional ephedrine boluses of 5 mg repeated every three minutes with additional infusion of Ringer solution.
2. Bradycardia (<55 beats per minute): bolus of atropine 0,5 mg, repeated every one minute until heart rate frequency is more than 55 beats per minute or overall amount of 2 mg atropine is reached.

Participants have their blood pressure taken every 5 minutes, their cardiac output and heart rate frequency measured using thoracic electrical bioimpedancy using a AESCULON, OSYPCA MEDICAL, 2011 monitor at baseline for 15 minutes before and 30 minutes after subarachnoidal anaesthesia.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Blood pressure is measured using oscylometric measurement with an Aesculon, Osypca Medical, 2011 monitor at baseline for 15 minutes before and 30 minutes after subarachnoidal anaesthesia
2. Cardiac output is measured using thoracic electrical bioimpedancy using an Aesculon, Osypca Medical, 2011 monitor at baseline for 15 minutes before and 30 minutes after subarachnoidal anaesthesia
3. Heart rate frequency is measured using thoracic electrical bioimpedancy using an Aesculon, Osypca Medical, 2011 monitor at baseline for 15 minutes before and 30 minutes after subarachnoidal anaesthesia

Secondary outcome measures

1. Systemic Vascular Resistance (SSVR) is measured using thoracic electrical bioimpedancy using an Aesculon, Osypca Medical, 2011 monitor at baseline for 15 minutes before and 30 minutes after subarachnoidal anaesthesia
2. Left Cardiac work (LCSW) is measured using thoracic electrical bioimpedancy using an Aesculon, Osypca Medical, 2011 monitor at baseline for 15 minutes before and 30 minutes after subarachnoidal anaesthesia
3. Potential rescue management is recorded for each patient by the investigator at the anesthetic documentation after subarachnoidal anaesthesia

Overall study start date

01/08/2016

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Aged 50 years and over
2. ASA II-III
3. Patients scheduled for lower extremity surgery

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

90

Total final enrolment

70

Key exclusion criteria

1. Heart failure (known ejection fraction less than 30%)
2. Manifest heart valve disease
3. Arrhythmias
4. Ischaemic heart disease
5. Manifest liver disease
6. Kidney disease (serum creatinine more than 120 mmol/L)
7. BMI more than 30
8. Drug abuse (including alcohol)
9. Chronic use of benzodiazepines, opioids or other psychotropic substances
6. Drug abuse (including alcohol)
7. Chronic use of benzodiazepines, opioids or other psychotropic substances

Date of first enrolment

01/07/2017

Date of final enrolment

01/12/2017

Locations

Countries of recruitment

Slovenia

Study participating centre

University Medical Centre Maribor
Ljubljanska ulica 5
Maribor
Slovenia
2000

Sponsor information

Organisation

University Medical Centre Maribor

Sponsor details

Medical research department
Ljubljanska ulica 5
Maribor
Slovenia
2000

Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Centre Maribor

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

01/02/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Miodrag Žunić.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/11/2019	15/11/2019	Yes	No