

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparing the different dosages of prophylactic phenylephrine infusion effect on hypotension in elderly patients under spinal anesthesia in orthopedic surgeries

Protocol summary

Study aim

The purpose of this study will be to assess the effect of different dosages of prophylactic phenylephrine infusion effect on hypotension in elderly patients under spinal anesthesia in orthopedic surgeries

Design

Clinical trial with two arm parallel groups, randomised trial with double blinded assessment. Study phase will be 2-3.

Settings and conduct

In Urmia Imam Khomeini hospital operating room the patients under spinal anesthesia in orthopedic surgeries will be divided into two parallel groups (30 patients each group). The drug will be administered by the nurse, the anesthesiologist will be unaware which patient will be assigned to which group. Drug containers will be identical and only the nurse will know about the contents of each of them, and finally, after collecting information by the resident in training in anesthesiology, the anesthesiology specialist will be informed of the group each patient is assigned to. Hemodynamic changes during surgery will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria : over 60 years, American Society of Anesthesiologists physical status classification I and II, Patients under spinal anesthesia Ages 1 to 60
Exclusion criteria: Heart rate less than 45, Drug sensitivity to local anesthetics, Existence of uncontrolled systemic diseases such as diabetes or high blood pressure, Heart disease such as heart failure or arrhythmias, History of neurological or psychological diseases, Existence of any contraindications to performing spinal anesthesia

Intervention groups

Intervention group(A): Phenylephrine will be injected intravenously in 10 cc syringes containing 10 mg / ml in 100 ml of normal saline and Intervention group(B): Phenylephrine will be injected intravenously in

10 cc syringes containing 10 mg / ml in 200 ml of normal saline immediately after changing position to supine position

Main outcome variables

Mean blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220612055143N1**

Registration date: **2022-06-18, 1401/03/28**

Registration timing: **prospective**

Last update: **2022-06-18, 1401/03/28**

Update count: **0**

Registration date

2022-06-18, 1401/03/28

Registrant information

Name

Mitra Golmohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 8967

Email address

mitragolmohammadi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the different dosages of prophylactic phenylephrine infusion effect on hypotension in elderly patients under spinal anesthesia in orthopedic surgeries

Public title

Evaluation the effect of different dosages of prophylactic phenylephrine infusion effect on hypotension during surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 60 years American Society of Anesthesiologists physical status classification I and II Patients under spinal anesthesia

Exclusion criteria:

Heart rate less than 45 Drug sensitivity to local anesthetics Existence of uncontrolled systemic diseases such as diabetes or high blood pressure Heart disease such as heart failure or arrhythmias History of neurological or psychological diseases Existence of any contraindications to performing spinal anesthesia

AgeFrom **60 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

The number of patients in this study will be 60. This number of patients will be exclusive randomly assigned into two groups of phenylephrine 10mg / ml in 100 ml of normal saline(group A) and phenylephrine 10mg / ml in 200 ml of normal saline (group B) using Random Allocation Software 2.0, and the target codes will be written and placed in sealed envelopes with sequential allocation using double-blind method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthesiologist will be unaware of which patient will be assigned to which group. phenylephrine syringes will be identical and only the operating room will knew about the contents of each of them, and finally, after collecting information from the anesthesia residents, the anesthesiologist will be informed of the group each

patient will be assigned to.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

Street address

Orjanse alley, Resalat blvd

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2022-05-28, 1401/03/07

Ethics committee reference number

1401.111.IR.UMSU.REC

Health conditions studied**1****Description of health condition studied**

blood pressure during surgery

ICD-10 code

I95.2

ICD-10 code description

Hypotension due to drugs

Primary outcomes**1****Description**

Mean blood pressure

Timepoint

In the first 10 minutes every minute and then every 5 minutes until the end of the operation

Method of measurement

None invasive blood pressure

2**Description**

Mean Pulse rate

Timepoint

In the first 10 minutes every minute and then every 5 minutes until the end of the operation

Method of measurement

Electrocardiogram

Secondary outcomes**1****Description**

nausea and vomiting

Timepoint

During operation

Method of measurement

patient observation

Intervention groups**1****Description**

Intervention group: Phenylephrine, manufactured by BB Pharma, will be injected intravenously in 10 cc syringes containing 10 mg / ml in 100 ml of normal saline immediately after changing position to supine position.

Category

Prevention

2**Description**

Intervention group: Phenylephrine, manufactured by BB Pharma, will be injected intravenously in 10 cc syringes containing 10 mg / ml in 200 ml of normal saline immediately after changing position to supine position.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Operating room, Khomeini Hospital

Full name of responsible person

Mitra Golmohammadi

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Ershad blvd, Modarres blvd

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emam-h-urm@umsu.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Saber Gholizadeh

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research@umsu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Mitra Golmohammadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

Mitra Golmohammadi

Position

Associate Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available