

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effect of ephedrine infusion on hemodynamic changes in the elderly undergoing spinal anesthesia

Protocol summary

Study aim

Effect of ephedrine infusion on hemodynamic changes in the elderly undergoing spinal anesthesia

Design

This is a randomized, single-blind clinical trial with parallel and control groups.

Settings and conduct

Patients will receive appropriate intervention at Imam Reza Hospital in Tabriz after being assigned to the relevant groups. Patients in the intervention group during spinal anesthesia will receive ephedrine after infusion and the control group will receive the placebo. Patients are blind during the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Minimum age 65 years, Candidate for Spinal Anesthesia Exclusion criteria: Diabetes Mellitus, Cardiovascular disease

Intervention groups

Participants will be randomly divided into two groups; anesthesia for all individuals in the fourth and fifth lumbar spines will be done: Intervention group: After blood pressure drop of more than 20%, they will receive vasopressor drug and will be given ephedrine infusion. Control group: After a blood pressure drop of more than 20%, they will receive placebo (normal saline serum) and given placebo as an infusion. Normal saline serum is manufactured by Iran Darou Company. It should be noted that ephedrine or placebo will be infused at 60 mg / hr. Ephedrine is a medicine manufactured by Iran Darou Company and infusion is started each time the patient's blood pressure drops and if healed, the infusion will be stopped. The infusion pump machine will be used to do this, which is a device manufactured by Zimmer in the US.

Main outcome variables

Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N15**

Registration date: **2019-12-22, 1398/10/01**

Registration timing: **prospective**

Last update: **2019-12-22, 1398/10/01**

Update count: **0**

Registration date

2019-12-22, 1398/10/01

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of ephedrine infusion on hemodynamic changes in the elderly undergoing spinal anesthesia

Public title

Ephedrine infusion during spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Minimum age 65 years Candidate for spinal anesthesia

Exclusion criteria:

Cardiovascular diseases Diabetes Mellitus

Age

From **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The dice throw method will be used for randomization.

The even number represents the individual in the intervention group and the odd number represents the individual in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

All participants will be given drug infusions or placebo (normal saline serum) in case of hypotension. The drug or placebo will be 50mm inside the syringe. The syringes are quite similar and their contents are colorless. The participant is unaware of the type of drug received and will be blind during the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2019-10-04, 1398/07/12

Ethics committee reference number

IR.TBZMED.REC.1398.733

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

Blood pressure

ICD-10 code

R03.0

ICD-10 code description

Elevated blood-pressure reading, without diagnosis of hypertension

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

Blood pressure

Timepoint

After spinal anesthesia, the patient's blood pressure will be measured every three minutes.

Method of measurement

Barometer

Secondary outcomes

empty

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

Intervention group: Participants in this group will be randomly assigned to spinal anesthesia after random assignment. In the first ten minutes, blood pressure will be measured every 1 minute and then every three minutes. If blood pressure drops below 20%, the infusion of ephedrine in the 50-mm syringe will begin at a rate of three milliliters per hour and will continue until the blood pressure returns to normal. During surgery, if the blood pressure drops more than 20%, the drug will be infused. The dose will be 60 mg per hour. The drug will be purchased from Iran Daroo Company .

Category

Treatment - Drugs

2**Description**

Control group: Participants in this group will be randomly assigned to spinal anesthesia after random assignment. In the first ten minutes, blood pressure will be measured every 1 minute and then every three minutes. If blood

pressure drops below 20%, placebo infusion will begin in a 50-mm syringe at a rate of three milliliters per hour and will continue until the blood pressure returns to normal. During surgery, if the blood pressure drops more than 20%, the placebo will be infused. In our study, placebo is a normal saline serum that will be purchased from Iran Daroo Company.

Category

Placebo

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

Imam Reza Hospital

Full name of responsible person

Parichehr Mazooji

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

6165665631

Phone

+98 21 3335 5921

Email

parimaz@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Tabriz University of Medical Sciences, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3335 7310

Email

Ajouyban@hotmail.com

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

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Parichehr Mazoji

Position

Doctor

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Iman Reza Hospital, Golgash Ave

City

East Azarbaijan

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3336 9586

Email

parimaz@gmail.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Parichehr Mazoji

Position

Doctor

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Imam Reza Hospital, Golgasht Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3334 7054

Fax**Email**

Parimaz@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parichehr Mazoji

Position

Doctor

Latest degree

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Street address

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Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3334 7054

Fax

Email

Parimaz@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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