

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of ephedrine and placebo on hemodynamic changes in patients undergoing percutaneous nephrolithotomy with spinal anesthesia

Protocol summary

Study aim

The purpose of this study will be to assess the effect of ephedrine and placebo on hemodynamic changes in patients undergoing percutaneous nephrolithotomy with spinal anesthesia

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 with undergoing percutaneous nephrolithotomy with spinal anesthesia 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. After surgery shoulder pain will be compared with each other.

Participants/Inclusion and exclusion criteria

Inclusion criteria :aged 20 to 60 years, American Society of Anesthesiologists physical status classification I and II, Patients under spinal anesthesia, Stones larger than 10 mm in lower calyx and large stones Impacted in proximal ureter Exclusion criteria:Patients with pilocalis stones larger than 20 mm and Extracorporeal Shock Wave Lithotripsy resistant 10-20 mm stones, patient with unmodified coagulopathy, patient with untreated active urinary tract infection, Patients with skeletal deformity, Patients with a history of drug allergy, In in patient with high volume bleeding and need for blood transfusion

Intervention groups

Intervention group: Will receive Ephedrine 10 mg before changing lithotomy position to supine.
Intervention group2: Will receive Placebo before changing lithotomy position to supine

Main outcome variables

Mean blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160430027677N21**

Registration date: **2022-02-28, 1400/12/09**

Registration timing: **prospective**

Last update: **2022-02-28, 1400/12/09**

Update count: **0**

Registration date

2022-02-28, 1400/12/09

Registrant information

Name

Shahryar Sane

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 4897

Email address

sane.sh@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of ephedrine and placebo on hemodynamic changes in patients undergoing percutaneous nephrolithotomy with spinal anesthesia

Public title
Evaluation the effect of ephedrine on intraoperative blood pressure

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
aged 20 to 60 years American Society of Anesthesiologists physical status classification I and II Patients under spinal anesthesia Stones larger than 10 mm in lower calyx and large stones Impacted in proximal ureter
Exclusion criteria:
Patients with pilocalis stones larger than 20 mm and Extracorporeal Shock Wave Lithotripsy resistant 10-20 mm stones patient with unmodified coagulopathy patient with untreated active urinary tract infection Patients with skeletal deformity Patients with a history of drug allergy patient with high volume bleeding and need for blood transfusion

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target 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 ephedrine (group H) and placebo (group P) 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. Ephedrine and placebo 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

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
research ethics committees of islamic Azad university_ Tabriz Branch
Street address
Pasdaran blvd, Islamic Azad university_ Tabriz Branch
City
Tabriz
Province
East Azarbaijan
Postal code
5157944533
Approval date
2021-09-14, 1400/06/23
Ethics committee reference number
IR.IAU.TABRIZ.rec.1400.082

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
During operation every 3 minutes after drug injection

Method of measurement
None invasive blood pressure

Secondary outcomes

1

Description
Pulse rate

Timepoint
During operation every 3 minutes after drug injection

Method of measurement

Electrocardiogram

2

Description

nausea and vomiting

Timepoint

During operation

Method of measurement

patient observation

Intervention groups

1

Description

Intervention group: Ephedrine drug with the name of BB Pharma manufacturer in the form of 5 cc syringes containing 5 ml solutions diluted with water, 10 mg of ephedrine prepared per 1cc will be injected intravenously immediately after changing the lithotomy position to the supine position. The injection will be given once.

Category

Prevention

2

Description

Control group: Placebo syringes are 5 cc syringes containing distilled water and immediately after changing the lithotomy position to the supine position, 1cc will be injected intravenously. The injection will be given once.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating room, Khomeini Hospital

Full name of responsible person

Shahryar Sane

Street address

Ershad blvd, Modarres blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber Gholizadeh

Street address

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

urmia 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

Shahryar Sane

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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