

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Investigating the Effect of Induced Hypotensive Anesthesia versus Normotensive Anesthesia on Perioperative Bleeding in Patients Undergoing Percutaneous Nephrolithotomy: A Randomized Controlled Clinical Trial

Protocol summary

Study aim

Determining the effect of induced hypotensive anesthesia against normotensive anesthesia on perioperative bleeding in patients undergoing percutaneous nephrolithotomy at Al-Zahra hospital

Design

A randomized clinical trial with a control group, parallel groups with interventions of normotensive and hypotensive anesthesia, double blind, randomized with random allocation software, phase two, with 32 participants

Settings and conduct

This study will be conducted at Al-Zahra Hospital, Isfahan in 2023. After selecting the allocation of patients to the intervention groups randomly, the amount of bleeding and other information related to the outcome will be collected during and after the surgery. Blinding: the patient, the doctor who collects the information (with the help of the anesthesiologist supervising the patient) and the statistician (by coding the data)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients candidate for percutaneous Nephrolithotomy (PCNL); Age of above 18 years;
Exclusion criteria: Coagulopathy; Anatomical disorders that interfere with the proper positioning of the patient; Any disease that makes inducing the controlled hypotension impossible during surgery; Single kidney; Ectopic kidney; Active infection of the urinary system; Pregnancy

Intervention groups

Control group (normotensive anesthesia): Administered general anesthesia with 4-5 mg/kg sodium thiopental, 3 microg/kg fentanyl, and 0.15 mg/kg cisatracurium.
Intervention group (induced hypotensive anesthesia): After anesthesia induction, continuous remifentanyl infusion at 0.2/mg/kg/min will induce hypotension,

adjusting to maintain mean arterial pressure between 65-75 mm Hg.

Main outcome variables

Perioperative blood loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150420021869N7**

Registration date: **2024-01-23, 1402/11/03**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-23, 1402/11/03**

Update count: **0**

Registration date

2024-01-23, 1402/11/03

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Induced Hypotensive Anesthesia versus Normotensive Anesthesia on Perioperative Bleeding in Patients Undergoing Percutaneous Nephrolithotomy: A Randomized Controlled Clinical Trial

Public title

The effect of induced hypotensive anesthesia on blood loss in percutaneous nephrolithotomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient candidate for percutaneous Nephrolithotomy (PCNL) Age of above 18 years

Exclusion criteria:

Coagulopathy Anatomical disorders that interfere with the proper positioning of the patient Any disease that makes inducing the controlled hypotension impossible during surgery Single kidney Ectopic kidney Active infection of the urinary system Pregnancy Hematological diseases Cardiovascular diseases Glomerular Filtration Rate of less than 60 cc/min

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: 62

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are allocated into either the intervention or control group using a non-stratified block randomization method to keep an even randomization ratio of (1:1). Random Allocation Software is used by our expert analytics to determine the list and group of patients. He is blinded to the selection process and pre-and post-operative assessments. The block size will be equal and is set to 4 and then the allocation code is set to sequential.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are kept uninformed about the use of controlled blood pressure during the procedure. To ensure blinding, two researchers conduct the interventions. A anesthesiologist or resident of anesthesiology, knowledgeable about the necessary interventions for each patient, carries out the procedures while monitoring the patient's condition. Simultaneously, another researcher, unaware of the specific interventions performed on each patient, assesses blood loss and gathers necessary information through patient examinations. Additionally, the coding of the investigated groups in the collected data is implemented to maintain blinding for the statistician.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

Street address

Hezar Jerib street

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Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-06-25, 1402/04/04

Ethics committee reference number

IR.MUI.MED.REC.1402.094

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

Calculus of kidney

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

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

Perioperative blood loss

Timepoint

Post operative

Method of measurement

After surgery, we add 1000 units of heparin to the collection bucket to prevent coagulation of the washing solution. Then 5cc of washing liquid is added to the vial of EDTA (ethylenediamine triacetic acid) to estimate hemoglobin. Hemocue method is used to estimate intraoperative bleeding. In this method, the amount of hemoglobin in the lavage fluid is multiplied by the total volume of the lavage fluid used, and the result is divided by the volume of serum hemoglobin before the operation, and thus the total amount of blood lost will be determined.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, general anesthesia is administered as a standard IV injection of 4-5 mg/kg of sodium thiopental, 3 µg/kg of fentanyl and 0.15 mg/kg of cisatracurium. In this group, in addition to remifentanyl anesthetic drugs, the dose of 0.2 µg/kg/min is started continuously, and then the infusion rate is changed to keep the MAP constant between 65-75 mm-hg.

Category

Treatment - Drugs

2

Description

Control group: In this group, general anesthesia is administered as a standard IV injection of 4-5 mg/kg of sodium thiopental, 3 µg/kg of fentanyl and 0.15 mg/kg of cisatracurium. Anesthesia is maintained by continuous inhalation of 60% air + 40% oxygen and 1-1.5% isoflurane, as well as intermittent bolus of 1-2 µg/kg fentanyl and 0.05 mg/kg atracurium.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Farshad Gholipour

Position

Assistant professor of Urology

Latest degree

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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