

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of lateral position after spinal anesthesia on the need for postoperative narcotics

Protocol summary

Study aim

Determining the effect of lateral position after spinal anesthesia on the need for postoperative narcotics

Design

Clinical trial with intervention and control groups, 69 patients sample size, Trial phase 2-3. Simple randomization will be done as a block randomization method.

Settings and conduct

69 participants with entry conditions, among the candidates for percutaneous nephrolithotomy surgery referred to Shahid Labafinejad Hospital in 2022, were randomly divided into two control and intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 and above; Candidate patients for percutaneous nephrolithotomy surgery; Candidate for spinal anesthesia; Patients with satisfaction to participate in the study Exclusion criteria: History of neurological diseases; diabetes; hypertension; History of drug and alcohol abuse; History of vascular disorders in the lower limbs; History of spine surgery; History of psychiatric diseases and psychological disorders; Patients dissatisfied with participation in the study

Intervention groups

Intervention group: After spinal anesthesia, they undergo percutaneous nephrolithotomy surgery in the lateral position. Control group: After spinal anesthesia, they undergo percutaneous nephrolithotomy in supine position.

Main outcome variables

The amount of narcotic needed after the operation; the first time of narcotic consumption; hemodynamics of the patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221109056450N1**

Registration date: **2023-01-19, 1401/10/29**

Registration timing: **retrospective**

Last update: **2023-01-19, 1401/10/29**

Update count: **0**

Registration date

2023-01-19, 1401/10/29

Registrant information

Name

Alireza Jaffari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2360 2280

Email address

alirezajaffari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-20, 1401/09/29

Expected recruitment end date

2023-01-19, 1401/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lateral position after spinal anesthesia on the need for postoperative narcotics

Public title

The effect of lateral position after spinal anesthesia on the consumption of narcotic drugs after surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 18 and above Candidate patients for percutaneous nephrolithotomy surgery Candidate for spinal anesthesia Patients with satisfaction to participate in the study
Exclusion criteria:
 History of neurological diseases, diabetes, hypertension History of drug and alcohol abuse History of vascular disorders in the lower limbs History of spine surgery History of psychiatric diseases and psychological disorders Patients dissatisfied with participation in the study

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **69**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done as a block randomization method. So, initially, in the Excel software, there are 6 blocks of 4 as (AA, BB), (BB, AA), (AB, BA), (BA, AB). (AB, AB), (BA, BA) are prepared and then these blocks will be arranged from one to six. A is the confirmation of the treatment or intervention group and B is the confirmation of the control group. Then one of these blocks will be randomly selected and based on the sequence of letters A and B in the selected block, the eligible people will be assigned to the treatment or control groups. The random process of selecting blocks and assigning people to the intervention and control groups will continue until the desired sample size is reached.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of

Medical Sciences

Street address

Tabnak Street.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-08-22, 1398/05/31

Ethics committee reference number

IR.SBMU.MSP.REC.1398.431

Health conditions studied

1

Description of health condition studied

Complications of spinal anesthesia

ICD-10 code

T88.59

ICD-10 code description

Other complications of anesthesia.

Primary outcomes

1

Description

Pain level

Timepoint

15, 30, 45, 60, 95, 105 and 120 minutes after the surgery

Method of measurement

Visual analog scale (VAS) (0 None; 1-3 Mild; 4-7 Moderate; 8-10 Severe)

2

Description

The amount of narcotic drug consumption after the surgery

Timepoint

15, 30, 45, 60, 95, 105 and 120 minutes after the surgery

Method of measurement

Patient file

3

Description

The first time of narcotic drug use

Timepoint

After entering recovery and within 120 minutes after the surgery

Method of measurement

Patient file

4

Description

Hemodynamic status of the patient
Timepoint
15, 30, 45, 60, 95, 105 and 120 minutes after the surgery
Method of measurement
Non-invasive monitoring device

Secondary outcomes

1

Description
Nausea and vomiting after the surgery
Timepoint
After entering recovery and within 120 minutes after the surgery
Method of measurement
Patient files

Intervention groups

1

Description
Intervention group: After spinal anesthesia, they undergo percutaneous nephrolithotomy surgery in the lateral position.
Category
Prevention

2

Description
Control group: After spinal anesthesia, they undergo percutaneous nephrolithotomy in supine position.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafinezhad Hospital
Full name of responsible person
Alireza Jaffari MD
Street address
9th Boostan Street, Pasdaran Street
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Tehran
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1666663111
Phone
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alirezajaffari@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi MD.
Street address
Shahid Arabi st., Yaman St., Shahid Chamran Expressway
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1985717443
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+98 21 2243 9781
Email
zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Alireza Jaffari MD
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Latest degree
Specialist
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

The whole data can be shared after unidentifiable people.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only available to scholars working in academic and academic institutions.

Under which criteria data/document could be used

Employed in research centers

From where data/document is obtainable

Person responsible for scientific inquiries

What processes are involved for a request to access data/document

Send email to person responsible for scientific inquiries (alirezajaffari@gmail.com)

Comments