

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 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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1666663111

Phone

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Email

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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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

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Specialist
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Person responsible for updating data

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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