

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of success and complication rates between patients undergoing percutaneous nephrolithotomy (PCNL) under general and spinal anesthesia in a randomized clinical trial

Protocol summary

Summary

The aim of this study is to compare success and complication rates of PCNL in patients undergoing general and spinal anesthesia in a single blinded randomised clinical trial . the population under study comprises all older than 16 years patients who are candidate for PCNL surgery for renal stone . exclusion criteria are being single kidney, ceatinin higher than 2.5, renal anatomic abnormalities and a history of ipsilateral renal surgery . sample size has been estimated 120. According to a previously established allocation sequence, patients are allocated to either type of general or spinal anesthesia before surgery. afterwards, surgical success and intraoperational and postoperational complication rates are compared between two types of anesthesia, also anesthetic complication rates will also be compared between general and spinal anesthesia .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111187457N6**
Registration date: **2012-02-19, 1390/11/30**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-02-19, 1390/11/30

Registrant information

Name

Shabnam Golshan

Name of organization / entity

Urology and Nephrology Research Center (UNRC)

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 7222

Email address

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Recruitment status

Recruitment complete

Funding source

Urology and Nephrology Research Center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of success and complication rates between patients undergoing percutaneous nephrolithotomy (PCNL) under general and spinal anesthesia in a randomized clinical trial

Public title

Success and complications of percutaneous nephrolithotomy (PCNL) under general and spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all the patients older than 16 years who present with pelvis and/or calyceal stone and are candidate for PCNL surgery. Exclusion criteria: 1- lack of consent for either of general or spinal anesthesia; 2-

complete staghorn stone defined as pelvic stone concomitant with at least three calyces stones' 3- single kidney or single functional kidney patients; 4- patients with a history of ipsilateral renal surgery; 5- patients with high serum creatinin levels (higher than 2.5) due to prerenal, renal or postrenal azotemia; 6- congenital anatomic abnormality in the kidney undergoing surgery (malrotation, pelvic kidney, horse-shoe kidney); 7- patients who are suitable only for one type of anesthesia due to medical conditions, body habitus (pinal deformity, difficult-to-intubate larynx), etc; 8- any history of hypersensitivity to remifentanyl, propofol, atracurium, spinal anesthesia material; 9- opioid or alcohol addiction and 10- BMI higher than 30

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urology and nephrology Research Center Ethics Committee

Street address

No#99, 9th Boostan, Pasdaran Ave.

City

Tehran

Postal code

Approval date

2011-12-22, 1390/10/01

Ethics committee reference number

21689

Health conditions studied

1

Description of health condition studied

renal stone

ICD-10 code

N 20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

Stone clearance

Timepoint

24 hours after intervention

Method of measurement

Abdominal X-ray

2

Description

Transfusion rate

Timepoint

From start of surgery until discharge

Method of measurement

Number of pack cells transfused

3

Description

Opioid requirement

Timepoint

Opioid required during the first 48 hours after procedure

Method of measurement

Infusion pump controlled by patient

4

Description

Volume of urinary leakage

Timepoint

During the time of hospitalization

Method of measurement

Amount of urinary leakage through nephrostomy tract

5

Description

Visceral injury

Timepoint

During the procedure

Method of measurement

According to the sign and symptoms of patient

6

Description

Hemoglobin changes

Timepoint

Before and 6 hours after procedure

Method of measurement

Mg/dL according to the lab data

7

Description

Serum creatinin changes

Timepoint

Before and 6 hours after procedure

Method of measurement

Mg/dL according to the lab data

Secondary outcomes

1

Description

Fluoroscopy time

Timepoint

At the end of procedure

Method of measurement

Time of exposure to X-ray

2

Description

Hospitalization time

Timepoint

From admission to discharge from hospital

Method of measurement

Days of hospitalization according to hospital file

Intervention groups

1

Description

In the intervention group in which PCNL will be performed under spinal anesthesia, while the patient is positioned in the ipsilateral decubitus, using a 25 gauge quincke needle 0.25 mg/kg of bupivacaine will be introduced into the thecal space . patient will remain in this position for 3 minutes and then surgery starts .

Category

Treatment - Surgery

2

Description

In control group in which PCNL will be performed under general anesthesia, anesthesia is induced with 2mg/kg of propofol plus 0.5 mg/kg of atracurium, then is continued with with 0.1 mg/kg.min of propofol plus 0.05 µg/kg.min of remifentanyl

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Labbafinejad hospital

Full name of responsible person

Akbar Nouralizadeh , Urologist , Associate professor

Street address

No#99, 9th Boostan, Pasdaran Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urology and nephrology research center

Full name of responsible person

Shabnam Golshan

Street address

No3103, 9th Boostan, Pasdaran Ave.

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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

Urology and nephrology research center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Labbafinejad Medical Center

Full name of responsible person

Dr Hossein Kilani

Position

MD, Resident of Urology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty