Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 anesthesic 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)

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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 ptients; 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, dificult-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 untill 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 contolled 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 accoding 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 quinke 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
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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