

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of efficacy and complications of tubeless Percutaneous Nephrolithotomy in prone and supine position under spinal anesthesia in adult patients

Protocol summary

Summary

In this randomized clinical trial 64 patients aged 18 years and over with renal or upper ureteral stones candidate for percutaneous nephrolithotomy (PCNL) that refer to Shahid Beheshti hospital of Yasuj after taking informed consent form and approval of ethics committee randomly assigned in one of two groups to undergo surgery in supine or prone position. Patients with severe cardiovascular or pulmonary disease, uncontrolled coagulopathy, pregnant patients and those with any contraindication for general or spinal anesthesia will be excluded. Basic serum samples including Hb and kidney function tests (BUN, Cr), urinalysis and urine culture will be checked for all of them. Then in Group 1 (prone position) after prep of patients under spinal anesthesia (2-2.5 milliliter of bupivacaine and 0.5 milliliter of fentanyl) ureteral catheter 5-6F will be inserted in ureter in the lithotomy position. Then the patient position will be changed in prone position and with fluoroscopic guidance PCNL will be performed using standard methods without nephrostomy tube. In second group (Supine position) under spinal anesthesia similar to the first group and after inserting ureteral catheter PCNL will be done same as first group in supine position. In the event of any adverse events operation will be terminated and standard treatment will be done. Twenty four hours after surgery Hb, BUN and Cr will be checked and in absence of fever, urine leakage or any complication patients will be discharged. Two week after surgery the patients visit again and ultrasonography and KUB will be performed for evaluating efficacy, success of operation and complications and data recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509111323N9**

Registration date: **2016-02-28, 1394/12/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-28, 1394/12/09

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 74 3334 6070

Email address

dr.mehrabi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Yasuj University of Medical Sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2015-10-01, 1394/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and complications of tubeless

Percutaneous Nephrolithotomy in prone and supine position under spinal anesthesia in adult patients

Public title

Position and Percutaneous Nephrolithotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with renal or upper ureteral stones more than 15-20 mm aged 18 years and over candidate for PCNL (stones resistant to ESWL, multiple stones and staghorn kidney stones); Exclusion criteria: Patients with severe cardiovascular or pulmonary disease, uncontrolled coagulopathy, scoliosis or kyphosis, pregnant patients and those with any contraindication for general or spinal anesthesia

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

For randomization of patients to one of two groups of interventions block randomization with four block were used.

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of medical sciences

Street address

Mottahari street, Yasuj University of medical sciences, Yasuj, Iran

City

Yasuj

Postal code

Approval date

2014-07-23, 1393/05/01

Ethics committee reference number

p/23/8/2903

Health conditions studied

1

Description of health condition studied

Renal and ureteral stones

ICD-10 code

N20.2

ICD-10 code description

Calculus of kidney with calculus of ureter

Primary outcomes

1

Description

Success rate of operation and stone crushing

Timepoint

during operation and two week later

Method of measurement

observation by nephroscope and fluoroscopy during operation and with sonography and KUB two weeks later

Secondary outcomes

1

Description

Any complications of surgery (Pulmonary, vascular, visceral, neurologic and others)

Timepoint

During operation to two week later

Method of measurement

Report of patients and physician and observation with examination of patients lung, checking sensory and motors and pulse of extremities and ultrasonography

Intervention groups

1

Description

Performing tubeless percutaneous nephrolithotomy (Tubeless) under spinal anesthesia in prone position in Group 1 (prone position) after prep of patients under spinal anesthesia (2. 2.5 milliliter of bupivacaine and 0.5 milliliter of fentanyl) ureteral catheter 5.6 F will be inserted in ureter in the lithotomy position. Then the patient position will be changed in prone position and with fluoroscopic guidance PCNL will be performed using standard methods without nephrostomy

tube
Category
Treatment - Surgery

2

Description

Performing tubeless percutaneous nephrolithotomy(Tubeless) under spinal anesthesia in supine position in Group 2 (Supine position) after prep of patients under spinal anesthesia (2, 2.5 milliliter of bupivacaine and 0.5 milliliter of fentanyl) ureteral catheter 5,6F will be inserted in ureter in the lithotomy position .Then the patient position will be changed to supine position and with fluoroscopic guidance PCNL will be performed using standard methods without nephrostomy tube.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shaheed Behehti hospital of Yasuj
Full name of responsible person
Dr Sadrollah Mehrabi
Street address
Shaheed Behehti Hospital, Montazeri street, Yasuj, Iran
City
Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Yasuj University of Medical Sciences
Full name of responsible person
Dr Mehdi Akbartabar
Street address
Mottahari street, Vice Chancellor for research of Yasuj University of Medical Sciences,Yasuj, Iran
City
Yasuj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Yasuj University of Medical Sciences
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
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Person responsible for scientific inquiries

Contact

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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