Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy and complications of PCNL under General and Spinal anesthesia

Protocol summary

Summary

In a randomized clinical trial, one hundred patients older than 18 years old who was referred to Shaheed Mofateh clinic of Yasuj with renal or upper ureteral stone larger than 20 millimeter and were candidate for PCNL, were randomly assigned in one of two groups. The intervention and control group underwent PCNL under spinal anesthesia and general anesthesia, respectively. Written informed consent was only given from the patients who were allocated to the intervention group. Spinal anesthesia was induced with Marcaine (15 mg) and Fentanyl (0.25 µg) injected intrathecally at the L3-L4 interspaces and head of bed tilted down for 5-10 minutes with checking level of anesthesia. Conscious sedation, during PCNL, was obtained with intravenous diazepam (2.5 mg or Midazolam (1 to 1.5 mg in bolus). General anesthesia was performed for the control group. PCNL was done under guide of fluoroscopy by standard technique and homodynamic and anesthetic variables such as oxygen saturation, duration of operation, hypotension and toleration of patients with complications and coast of anesthetic drugs are recorded during operation. Efficacy of procedure was evaluated by comparing clearance of system and residual stone between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138707201323N1**
Registration date: **2009-12-20, 1388/09/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-12-20, 1388/09/29

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 6070

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dr.mehrabi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice-Chancelor for Research, Yasuj University of Medical Sciences and Health Services

Expected recruitment start date

2008-02-01, 1386/11/12

Expected recruitment end date

2009-12-30, 1388/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and complications of PCNL under General and Spinal anesthesia

Public title

Comparison of efficacy and complications of PCNL under General and Spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 18 years, presence of renal or upper ureteral stone, candidate for PCNL (multiple stones, staghorn stones, calyceal diverticule stones, stone which are resistant to ESWL, lower pole

renal stone larger than >15 mm and other renal stone larger than 25 mm, upper ureteral stone >20mm, Having informed consent Exclusion criteria: Any contraindication for regional anesthesia, presence of coagulopathy, acute infection ore urosepsis, presence of acute renal failure

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **1**

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
Ethics committee of Yasuj University of Medical Sciences

Street address
Imam Sajad hospital, Yasuj university of medical science,

City
Yasuj

Postal code
41417-75917

Approval date
2008-02-09, 1386/11/20

Ethics committee reference number
p/23/5/2619

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

Timepoint
during operation and two week later

Method of measurement
observation by nephroscope and fluroscopy during operation and with sonography and KUB two weeks later

Secondary outcomes

1

Description
Any complications of surgery

Timepoint
during operation to one week later

Method of measurement
report of patients and observation with examination of patients

Intervention groups

1

Description
Performing PCNL under spinal anesthesia at the prone position

Category
Treatment - Surgery

2

Description
Performing PCNL under general anesthesia at the prone position

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shaheed Behehti Hospital

Full name of responsible person
Dr Sadrollah Mehrabi

Street address
Shaheed Beheshti hospital, Montazeri street,Yasuj

City
Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research manager, Yasuj University of Medical Sciences
Full name of responsible person
Dr Mehdi Akbartabar
Street address
Emam Sajad Hospial, Yasuj University of Medical Sciences
City
Yasuj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research manager, 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
Yasuj university of medical science
Full name of responsible person
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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