

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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 hemodynamic and anesthetic variables such as oxygen saturation, duration of operation, hypotension and toleration of patients with complications and cost 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)

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Recruitment status

Recruitment complete

Funding source

vice-Chancellor 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 or 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 Hospiat, 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

Dr Sadrollah Mehrabi

Position

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Web page address**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