

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### A Study on Comparative Outcomes of Totally Ultrasonography-Guided Percutaneous Nephrolithotomy in Prone versus Flank Position: A Randomized Clinical Trial

#### Protocol summary

##### Study aim

This study was designed to evaluate the outcomes of flank versus prone position in patients underwent ultrasonic-guided PCNL (percutaneous nephrolithotomy) for treatment of large kidney stones.

##### Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

##### Settings and conduct

This prospective randomized clinical trial was conducted from Jul 2016 to march 2019 in the department of Urology, Labbafinejad University hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran. Based on the table of random numbers generated by random allocation software in regard to simple random allocation. The principle analyzer assigned patients to either the flank group or the prone group and surgeries were conduct by the endourologist surgeon.

##### Participants/Inclusion and exclusion criteria

Patients with kidney stones larger than two cm were included in the study. Exclusion criteria contain pregnancy, acute urinary tract infection (UTI), coagulopathy

##### Intervention groups

A standardized PCNL (percutaneous nephrolithotomy) procedure was performed in all cases. Briefly, in the lithotomy position under general anesthesia a 6F ureteral catheter was inserted into renal pelvis with cystoscopy then the patient repositioned to standard flank position in flank and prone position in prone group (control group).

##### Main outcome variables

Success rate was our primary outcome. Success rate was defined as stone free rate plus stone burden < 4mm.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200902048597N1**

Registration date: **2020-11-21, 1399/09/01**

Registration timing: **retrospective**

Last update: **2020-11-21, 1399/09/01**

Update count: **0**

##### Registration date

2020-11-21, 1399/09/01

##### Registrant information

##### Name

Mehdi Dadpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2360 2220

##### Email address

mehdi.dadpour@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-07-22, 1395/05/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

2016-07-22, 1395/05/01

##### Actual recruitment end date

2019-03-21, 1398/01/01

##### Trial completion date

2019-03-21, 1398/01/01

## Scientific title

A Study on Comparative Outcomes of Totally Ultrasonography-Guided Percutaneous Nephrolithotomy in Prone versus Flank Position: A Randomized Clinical Trial

## Public title

PCNL ultrasonography guided in Prone versus Flank Position

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with kidney stones larger than two cm were included in the study

### Exclusion criteria:

pregnancy acute urinary tract infection coagulopathy

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **200**

More than 1 sample in each individual

Number of samples in each individual: **100**

100 patients underwent PCNL in flank position and 100 patients underwent PCNL in prone position

Actual sample size reached: **200**

More than 1 sample in each individual

Actual sample size in each individual: **100**

100 patients underwent PCNL in flank position and 100 patients underwent PCNL in prone position

## Randomization (investigator's opinion)

Randomized

## Randomization description

Based on the table of random numbers generated by random allocation software in regard to simple random allocation

## Blinding (investigator's opinion)

Double blinded

## Blinding description

participants (the patients) and the surgeon

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Urology and Nephrology research center, Shahid Beheshty University of Medical Sc

##### Street address

9th Boustan, Pasdaran Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1666663111

#### Approval date

2016-06-07, 1395/03/18

#### Ethics committee reference number

IR.SBMU.UNRC.1395.4

## Health conditions studied

### 1

#### Description of health condition studied

kidney stone

#### ICD-10 code

N20.0

#### ICD-10 code description

Calculus of kidney

## Primary outcomes

### 1

#### Description

stone free rate

#### Timepoint

day 1, 2 week, 3 month

#### Method of measurement

sonography, KUB, CT scan

## Secondary outcomes

### 1

#### Description

nephrostomy time

#### Timepoint

day 1

#### Method of measurement

time

### 2

#### Description

post-operative hemoglobin and Creatinine

#### Timepoint

day2

## Method of measurement

lab

### 3

#### Description

hospital stay

#### Timepoint

day

#### Method of measurement

days of hospitalization

## Intervention groups

### 1

#### Description

Intervention group: sonography-guided percutaneous nephrolithotomy in flank position

#### Category

Treatment - Surgery

### 2

#### Description

Control group: sonography-guided percutaneous nephrolithotomy in prone position

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Labbafinejad hospital

##### Full name of responsible person

Mohammad Hadi Radfar

##### Street address

9th Boostan, Pasdaran Ave

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##### Email

mehdi.dadpour@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zerghi

##### Street address

9th Boostan Pasdaran Ave

##### City

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##### Province

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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

Shahid Beheshti University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Mehdi Dadpour

##### Position

Urologist

##### Latest degree

Specialist

##### Other areas of specialty/work

Urology

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Urology and Nephrology Research Center, 9th Boustan, Pasdaran Ave, Tehran, Iran

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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**Latest degree**  
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**Email**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

sharing data is available after publishing

### When the data will become available and for how long

it will be available at 2020

### To whom data/document is available

for people working in academic institutions

### Under which criteria data/document could be used

similar project

### From where data/document is obtainable

without permission

### What processes are involved for a request to access data/document

get permission from corresponding author

### Comments