Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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), coagolopathy

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 coagolopathy
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
City
Tehran
Province
Tehran
Postal code
1666663111
Phone
+98 21 2360 2220
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
Tehran
Province
Tehran
Postal code
1666663111
Phone
+98 21 2360 2220
Email
mehdi.dadpour@sbmu.ac.ir
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
Street address
Urology and Nephrology Research Center, 9th Boustan, Pasdaran Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1666663111
Phone
+98 21 2360 2220
Fax
Email
mehdi.dadpour@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

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mehdi.dadpour@sbmu.ac.ir

Person responsible for updating data

Contact
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Shahid Beheshti University of Medical Sciences
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Mehdi Dadpour
Position
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mehdi.dadpour@sbmu.ac.ir

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