Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Percutaneous nephrolithotomy results in standard method and low radiation method under fluoroscopic guide in a single blinded randomized study with two paralel groups

Protocol summary

Study aim
Comparison of Percutaneous nephrolithotomy results in standard method and low radiation method under fluoroscopic guide in a single blinded randomized study with two paralel groups

Design
A randomized controlled clinical trial with parallel groups,one side is blind, with stratified random sampling on 46 patients, a random number table was used for randomization

Settings and conduct
Patients in two centers of Shahid Hasheminejad Hospital and Firoozgar Hospital are divided into two groups using block randomization method and each group is performed by a similar surgeon under two different PCNL techniques. in the standard PCNL technique, all steps are performed under fluoroscopy and radiation guidance, but in the radiation reduction technique, we intend to reduce the amount of radiation in parts of this method based on the sense of touch and the size of the device.Patients are anesthetized at the time of surgery and will therefore be blind to the study group. Results such as the amount of residual rock and complications will be reviewed by an uninformed resident of the study group. Allocation concealment is done by the head nurse before transfer to the operating room and is done without the knowledge of the researcher.

Participants/Inclusion and exclusion criteria
People more Than 18 years old With Renal Stone More Than 2CM In diameter Inter To Study Pepole With BMI More Than 39, Abnormal Anatomy Of The Kidney And Having More Than one Acsses To Get to Renal Pyelocaliceal System Exclode From Study

Intervention groups
One Group Underwent PCNL With Standard Method And Another One Underwent PCNL With Low Radiation Method Under Fluoroscopic Guide

Main outcome variables
X ray time during surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210316050721N1**
Registration date: **2022-12-21, 1401/09/30**
Registration timing: **prospective**

Last update: **2022-12-21, 1401/09/30**
Update count: **0**

Registration date
2022-12-21, 1401/09/30

Registrant information

Name
Behnam Shakiba

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8214 1301

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shakiba.b@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-03-02, 1401/12/11

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Percutaneous nephrolithotomy results in standard method and low radiation method under fluoroscopic guide in a single blinded randomized study with two paralel groups

Public title

Comparison of standard Percutaneous Nephrolithotomy and low flouro Percutaneous Nephrolithotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Renal stones more than 2 Cm in diameter

Exclusion criteria:

more than one access tract for login to pyelocaliceal system Pepole with morbid obesity (BMI more than 39) Abnormal anatomy of kidney

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Baseline data will be obtained before randomization. Enrolled patients who provide informed consent will be block randomized (1:1) to an intervention or control arm using this site:(http://sealedenvelope.com) .

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are anesthetized at the time of surgery and will therefore be blind to the study group. Results such as the amount of residual stones and complications will be reviewed by an uninformed resident of the study group. Allocation concealment is done by the head nurse before transfer to the operating room and is done without the knowledge of the researcher

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Medicine - Iran University of Medical Sciences (Research Ethics Committee)

Street address

Hasheminejd Kidney Center, Vali-nejad Str., Vanak Sq. Vali-e-asr Boul

City

Tehran

Province

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Postal code

۱۹۶۹۷۱۴۷۱۳

Approval date

2021-09-25, 1400/07/03

Ethics committee reference number

IR.IUMS.FMD.REC.1400.423

Health conditions studied

1

Description of health condition studied

Renal stone

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

X ray time during surgery

Timepoint

intra operation

Method of measurement

fluoroscopic time

Secondary outcomes

1

Description

Bleeding

Timepoint

Before intervention and day after surgery

Method of measurement

Hemoglobin

2

Description

stone free rate

Timepoint

1 week after surgery

Method of measurement
CT Scan or sonography plus KUB

3

Description
Duration of Percutaneous nephrolithotomy
Timepoint
During surgery
Method of measurement
minute

4

Description
Dose of radiation
Timepoint
During surgery
Method of measurement
Microgray per minute

5

Description
Time of getting acsses into renal pyelocaliceal system
Timepoint
During surgery
Method of measurement
minute

6

Description
Gender
Timepoint
Befor surgery
Method of measurement
Female or male

7

Description
Age
Timepoint
Befor surgery
Method of measurement
Number

8

Description
Stone measurement
Timepoint
Befor surgery
Method of measurement
Centimeter(measured by Spiral abdomenopelvic CT scan without contrast)

9

Description
Renal stone location
Timepoint
Before surgery
Method of measurement
Superior, middle, inferior calyces or renal pelvic or mix of them

10

Description
Body mass index
Timepoint
Before surgery
Method of measurement
Body mass divided by the square of the body height(Kg/m2)

11

Description
Complications of surgery
Timepoint
1 weeks after surgery
Method of measurement
The Clavien-Dindo Classification

Intervention groups

1

Description
Intervention group:The patient is first placed under general anesthesia and then in lithotomy posiotion , a 5 french(Fr) ureteral catheter inserted into the ureter of the desired side using a 8 Fr rigid urethroscope. The patient is then placed in the prone position. After the preb and drep , targeted calix is identified with fluoroscopy orientation of the line of puncture is performed using a triangulation technique. The C-arm is moved back and forth between 2 positions, that is 1 parallel and 1 oblique to the line of puncture. After the proper orientation of the line of puncture is obtained, ventilation is suspended in full expiration. Retrograde instillation of contrast dye allows collecting system opacification and distention. during continuous fluoroscopic radiation an 18 gauge needle is advanced toward the desired calix in the oblique position to gauge the depth of puncture. After accessing the pyelocaliceal system , a A0.038-inch hydrophilic nitinol wire is inserted. Aspiration of urine verifies proper caliceal puncture. after that with a single shot ray, the correct location of the guide wire is ensured. We measure the amount of needle entry and then enter the dilator 8 Fr using the needle size with the same angle and direction to the measured amount, then we check the correct location with a single shot ray.We measure input of the dilator and because the diameter of the primary dilator is more than the antenna, we gently slide the antenna on the guide wire based on the sense of touch and the size of The primary dilator and enter the system. Then insert the dilator 28 or 30 Fr according to the desired size and check its location again using single Shot Ray. Finally, we insert the Amplatz working sheath slowly according to the size difference with the last dilator, which there is no need to re-check its location. Finally, after confirming the

correct entry into wanted pyelocaliceal system (by watching urine and fluid injected into the ureteral catheter), the patient undergoes PCNL using a 24 Fr nephroscope , otherwise, the location will be corrected again.

Category

Treatment - Surgery

2

Description

Control group:The patient is first placed under general anesthesia and then in lithotomy posiotion , a 5 french(Fr) ureteral catheter inserted into the ureter of the desired side using a 8 Fr rigid urethroscope. The patient is then placed in the prone position. After the preb and drep , targeted calix is identified with fluoroscopy orientation of the line of puncture is performed using a triangulation technique. The C-arm is moved back and forth between 2 positions, that is 1 parallel and 1 oblique to the line of puncture. After the proper orientation of the line of puncture is obtained, ventilation is suspended in full expiration. Retrograde instillation of contrast dye allows collecting system opacification and distention. An 18 gauge needle is advanced toward the desired calix in the oblique position to gauge the depth of puncture. Continuous fluoroscopic monitoring is performed to ensure that the needle maintains the proper trajectory . aspiration of urine verifies proper caliceal puncture. A0.038-inch hydrophilic nitinol wire is then passed through the needle and into the collecting system.after that with a single shot ray, the correct location of the guide wire is ensured.under fluoroscopic guidance an attempt is made to advance the glidewire down the ureter. An 8Fr fascial dilator is passed into the calix, followed by a 5Fr Cobra tipped angiographic catheter.then we gently slide the antenna on the guide wire and we check it with fluoroscopic guidance.Then insert the dilator 28 or 30 Fr according to Continuous fluoroscopic monitoring. An Amplatz working sheath is placed following dilator of the tract to 30Fr.Finally, after confirming the correct entry into wanted pyelocaliceal system (by watching urine and fluid injected into the ureteral catheter), the patient undergoes PCNL using a 24 Fr nephroscope , otherwise, the location will be corrected again.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Hasheminejad hospital

Full name of responsible person

Behnam Shakiba

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Shahid Hasheminejad hospital, Shahid Valinejad Alley., Valiasr Street., Tehran

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Email

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2

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

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Firozgar hospital, Beh Afarin Street., Karim Khan Street., Valiasr Square., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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
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Full name of responsible person
Behnam Shakiba
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available