

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 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 Accses To Get to Renal Pyelocaliceal System Exclude 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

Email address

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

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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 access into renal pyelocaliceal system

Timepoint

During surgery

Method of measurement

minute

6**Description**

Gender

Timepoint

Before surgery

Method of measurement

Female or male

7**Description**

Age

Timepoint

Before surgery

Method of measurement

Number

8**Description**

Stone measurement

Timepoint

Before 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 position, 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 prep 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 position , 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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2**Recruitment center****Name of recruitment center**

Firoozgar hospital

Full name of responsible person

Behnam Shakiba

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Department of Urology, Firoozgar hospital, Behafarin St., Karimkhan Ave.

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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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Behnam Shakiba

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Province**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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Resident

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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