Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation of access to kidney stones in patients candidate for PCNL surgery using 3D technology in comparison with X-ray Fluorescopy

Protocol summary

Study aim
Evaluation of access to kidney stones in patients candidate for PCNL surgery using 3D technology in comparison with X-ray Fluorescopy

Design
Using the online site sealedenvelop.com (the site for sequencing block randomization) The four blocks are randomly assigned to patients in two groups: A: PCNL surgery using three-dimensional technology, and B: PCNL surgery using X-ray fluoroscopy. The order in which the patients are placed to operation model is provided to the technician. The study is Double blind. (Patient and surgeon) 48 patients referred to Sinai Hospital (with ethical consent) are studied. The study is an intervention, phase 3, parallel and therapeutic.

Settings and conduct
This clinical trial will be performed on 82 patients at Sina Hospital. Double blind(Patient and surgeon) Technician (importer of patients in each group based on random blocks) Random blocks, four blocks randomly from patients groups: A: PCNL surgery using three-dimensional technology, and B: PCNL surgery using X-ray fluoroscopy. 12 quadruple blocks are made which are placed in separate envelopes. Randomized blocks are given to a technician.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with kidney stones larger than 15 mm Indications for PCNL surgery Exclusion criteria: Patient dissatisfaction with participation in the research project Existence of surgical contraindication or CT scan

Intervention groups
Intervention group 1: PCNL surgery using three-dimensional technology Intervention group 2: PCNL surgery using X-ray fluoroscopy

Main outcome variables
The treatment of stones

General information

Reason for update

Acronym
Percutaneous Nephrolithotomy (PCNL)

IRCT registration information
IRCT registration number: **IRCT20200905048625N1**
Registration date: **2020-09-14, 1399/06/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-14, 1399/06/24**
Update count: **0**

Registration date
2020-09-14, 1399/06/24

Registrant information

Name
seyed reza hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6634 8560

Email address
srhoseini@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-31, 1399/06/10

Expected recruitment end date
2021-01-29, 1399/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of access to kidney stones in patients candidate for PCNL surgery using 3D technology in comparison with X-ray Fluorescopy

Public title
Access to kidney stones in PCNL surgery using two methods of 3D technology and X-ray fluoroscopy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with kidney stones larger than 15 mm Indications for PCNL surgery
Exclusion criteria:
Patient dissatisfaction with participation in the research project Existence of surgical contraindication or CT scan

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
The present study is a double-blind randomized clinical trial. For randomization, the blanced block randomization method is used to generate four blocks. Intervention group A and control group B have been determined.According to the randomization method, we expect the two groups to differ by a maximum of 2 people in terms of the number of people assigned. After the methodologist prepares the randomization sequence using the sealedenvelope online site, the generated sequence will be made available to a technician outside the research team.Quadruple blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected and the type of patient group is informed to the research team through a trained technician.The patient is placed in PCNL surgery using 3D technology or in X-ray Fluorescopy group based on the randomly selected envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients who have given their consent to participate in the study and Therapist To perform the blinding process, envelopes related to the type of intervention are provided only to the technician. The physician is not informed of the type of intervention (PCNL surgery using 3D technology or in X-ray Fluorescopy group) (to avoid bias).

Placebo
Not used

Assignment
Parallel

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee for Research in Tehran University of Medical Sciences

Street address
Room 604, Sixth Floor, medical University Tehran, Central Staff Building, Keshavarz Blvd., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2020-08-27, 1399/06/06

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.373

Health conditions studied

1

Description of health condition studied
kidney stones

ICD-10 code
N21

ICD-10 code description
Calculus of lower urinary tract

Primary outcomes

1

Description
kidney stone removal

Timepoint
once a month

Method of measurement
CT-scan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: PCNL surgery using three-dimensional technology -After the initial examination, all patients will have a CT scan without contrast of the abdomen and pelvis to evaluate the condition of the kidney stones (including size, exact location, angle of position), pelvic position, general anatomy of the abdomen and kidneys. CT scan images of patients are entered into Mimix software and a three-dimensional model of the kidney is designed and drawn from CT scan images. Using a 3D digital printer, a three-dimensional model of a kidney, which also includes a kidney stone, is made accurately and in accordance with the actual size, and finally, it is provided to the surgeon. 3D model before PCNL operation by surgeon, examination and preoperative planning for proper access to the stone site, will be done before the actual operation. PCNL surgery will then be performed to treat kidney stones in patients. -Variables of age, sex, pre- and postoperative serum creatinine, pre- and postoperative blood hemoglobin, postoperative bleeding, post-operative blood transfusion need, total PCNL surgery time, stone access time and stone profile will be recorded.

Category

Treatment - Surgery

2

Description

Intervention group: PCNL surgery using X-ray fluoroscopy - PCNL is performed using X-ray fluoroscopy to remove kidney stones by making a small hole through the skin. - This procedure is usually performed under general anesthesia or spinal anesthesia.Technically, in the PCNL method, the needle is passed through the skin to the kidney.The position of the needle is followed by fluoroscopy. With the help of a needle, a guide wire is inserted into the kidney.The needle is then removed, and while the guide wire is still inside the pelvis, a nephroscope is inserted to remove small stones.If the stone is large, it must first be crushed using ultrasound probes and then the stone pieces removed. -Variables of age, sex, pre- and postoperative serum creatinine, pre- and postoperative blood hemoglobin, postoperative bleeding, post-operative blood transfusion need, total PCNL surgery time, stone access time and stone profile will be recorded.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Seyed Reza Hosseini

Street address

Hassan Abad

City

Tehran

Province

Tehran

Postal code

١١٣٦٧٤٦٩١١

Phone

+98 21 6634 8500

Fax

+98 21 6634 8553

Email

srhoseini@tums.ac.ir

Web page address

http://sinahospital.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

Tehran. Keshavarz Boulevard, Quds Ave., Central University, Sixth Floor

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Fax

+98 21 8163 3686

Email

vcr@tums.ac.ir

Web page address

http://vcr.tums.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person
Dr Akram Mirzaei

Position
Researcher

Latest degree
Ph.D.

Other areas of specialty/work
Molecular Medicine

Street address
Urology Research Center- Sina Hospital - Imam Khomeini St

City
Tehran

Province
Tehran

Postal code
1136746911

Phone
+98 21 6634 8560

Fax
+98 21 6634 8561

Email
mirzaee.scholar@gmail.com

Web page address
https://URC@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Seyed Reza Hosseini

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Urology

Street address
Hassan Abad Asqu. Sina Hospital

City
تهران

Province
Tehran

Postal code
1136746911

Phone
+98 21 6634 8560

Fax
+98 21 6634 8560

Email
srhoseini@tums.ac.ir

Web page address
https://URC@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Akram Mirzaei

Position
Researcher

Latest degree
Ph.D.

Other areas of specialty/work
Medical Biology

Street address
Urology Research Center- Sina Hospital - Imam Khomeini St

City
Tehran

Province
Tehran

Postal code
1136746911

Phone
+98 21 6634 8560

Fax
+98 21 6634 8561

Email
mirzaee.scholar@gmail.com

Web page address
https://URC@tums.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
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
demographic information anonymously

When the data will become available and for how long
one year after publication

To whom data/document is available
Researchers working in academia, physicians, surgeons and hospitals

Under which criteria data/document could be used
Re-information for the purpose of clarification Using data by referring to the article's original Get permission from the author of the article and the presenter

From where data/document is obtainable
Sina Hospital, Urology Research Center, Dr. Seyed Reza Hosseini 00982166348560

What processes are involved for a request to access data/document
After reviewing the information by the administrator and

epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.

Comments

-