

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 balanced 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 sealed envelope 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

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
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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

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

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