

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of outcomes and complications of standard Percutaneous nephrolithotomy and multiaccess Percutaneous nephrolithotomy in patients with kidney stones

Protocol summary

Study aim

Comparison of outcomes of standard Percutaneous nephrolithotomy and multiaccess PCNL in Sina Hospital

Design

Using the online site sealedenvelop.com (the site for sequencing block randomization) blocks of size 4 are created for random allocation. The order in which the patients are allocated to operation model is provided to the technician. The study is double blind (Patient and surgeon). 50 patients referred to Sinai Hospital (with ethical consent) are studied. The study is an interventional, parallel and therapeutic.

Settings and conduct

This clinical trial will be performed on 50 patients with kidney stone at Sina Hospital. urology research center, Tehran, Iran. The study will be double blind (Patient and surgeon).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in the study, presence of renal stone. Exclusion criteria: Patients with cardiovascular disease, presence of acute renal failure, Patients with coagulation disorders, Age less than 18 years.

Intervention groups

Control group: standard Percutaneous nephrolithotomy treated. Intervention group: MULTIACCESS treated.

Main outcome variables

Treatment of kidney stones

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043991N16**

Registration date: **2022-05-16, 1401/02/26**

Registration timing: **prospective**

Last update: **2022-05-16, 1401/02/26**

Update count: **0**

Registration date

2022-05-16, 1401/02/26

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

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mkaghamir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-31, 1401/03/10

Expected recruitment end date

2022-12-31, 1401/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of outcomes and complications of standard Percutaneous nephrolithotomy and multiaccess Percutaneous nephrolithotomy in patients with kidney stones

Public title

Comparison of outcomes of standard Percutaneous nephrolithotomy and multiaccess

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study presence of renal stone

Exclusion criteria:

Patients with cardiovascular disease presence of acute renal failure Patients with coagulation disorders Age less than 18 years

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a double-blind randomized clinical trial. For randomization, the balanced block randomization method with blocks of size 4 is used. Intervention group A and control group B have been determined. After the methodologist prepares the randomization sequence using the sealdenvelop online site, the generated sequence will be made available to a technician outside the research team. Quadruple blocks (A or B) are placed inside the 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 MULTIACCESS or PCNL treatment 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 (MULTIACCESS or Percutaneous nephrolithotomy) 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 number 604, Sixth Floor, Central Staff Building, Tehran University of Medical Sciences, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-02-16, 1400/11/27

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1363

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

Control group: PCNL treated. In this method, the stone is accessed through a single access, the stones are removed after being crushed. Sometimes it is necessary to use multiple accesses to completely remove the stones.

Category

Treatment - Surgery

2

Description

Intervention group: Group 2: MULTIACCESS treated. In this method, access to different areas of the kidney is created through a single input. In short, with a single access and on different parts of the kidney, puncture and access to multiple stones is achieved.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Mohammad Kazem Aghamir

Street address

Urology Research Center - Sina Hospital - Hassan Abad St. - Tehran - Iran

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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

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

Medical Biology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Head of Urology Research Center

Latest degree

Specialist

Other areas of specialty/work

Urology

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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 DictionaryUndecided - 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 availableResearchers working in academia, physicians, surgeons
and hospitals**Under which criteria data/document could be used**Any analysis can be done with the consent of the main
researcher**From where data/document is obtainable**Sina Hospital, Urology Research Center, Head of Urology
Research Center: Dr. Seyed Mohammad Kazem Aghamir
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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