Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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+98 21 6634 8560

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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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Specialist
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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
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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