Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of success rate of kidney stone crushing based on body mass index and patient's condition during stone crushing

Protocol summary

Study aim
Evaluation of success rate of kidney stone crushing based on body mass index and patient's condition during stone crushing

Design
A clinical trial with two groups of patients: parallel, therapeutic, simple randomization. 84 patients referred to Sinai Hospital.

Settings and conduct
This clinical trial will be performed on 84 patients at Sina Hospital. Patients are divided into two groups of surgery and the quality of treatment results is evaluated. After completing the written consent, they will be placed in one of two groups of Supine and Prone Positions in Percutaneous Nephrolithotomy.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Consent to participate in the study. Candidate for prone PCNL surgery. Presence of Renal or Upper Ureteral Stone. Exclusion criteria: Patients with Cardiovascular disease. Patients with Coagulation disorders. Acute Infection Urosepsis. Presence of Acute Renal Failure.

Intervention groups
Intervention group1: Supine Positions in Percutaneous Nephrolithotomy. Intervention group2: Prone Positions in Percutaneous Nephrolithotomy.

Main outcome variables
Accuracy of calyx access, the success of extracorporeal lithotripsy in kidney stones in Supine and Prone Positions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190624043991N17**
Registration date: **2022-06-03, 1401/03/13**
Registration timing: **prospective**
Last update: **2022-06-03, 1401/03/13**
Update count: **0**

Registration date
2022-06-03, 1401/03/13

Registrant information

Name
Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6634 8560

Email address
mkaghamir@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-10, 1401/03/20

Expected recruitment end date
2023-02-09, 1401/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of success rate of kidney stone crushing based on body mass index and patient's condition during stone crushing

Public title
Evaluation of success rate of kidney stone crushing based on body mass index and patient's condition

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
presence of renal or upper ureteral stone Consent to participate in the study
Exclusion criteria:
Patients with cardiovascular disease presence of acute renal failure Patients with coagulation disorders acute infection Urosepsis

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
The present study is a randomized clinical trial. A simple randomization method and a random number table is used. In this way, a number will be selected randomly, if the number is even, the patient will enter the intervention group and if the number is odd, the patient will enter the second group. The researcher selects one of the numbers randomly, moves in one of the predetermined directions, records the numbers and assigns them to different groups. Even Number: Patients undergoing Percutaneous nephrolithotomy surgery (Supine Positions) odd Number: Patients undergoing Percutaneous nephrolithotomy surgery with (Prone Positions)

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committees in Medical Medical Research

Street address
Room 604, Sixth Floor, Central Staff Building, Tehran University of Medical Sciences, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2021-01-30, 1399/11/11

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.1035

Health conditions studied

1

Description of health condition studied
Renal and ureteral stones

ICD-10 code
N20.2

ICD-10 code description
Calculus of kidney with calculus of ureter

Primary outcomes

1

Description
Accuracy of calyx access

Timepoint
During operation

Method of measurement
Observation by nephroscope and fluroscopy during operation

Secondary outcomes

1

Description
The success of extracorporeal lithotripsy in kidney stones in Supine and Prone Positions

Timepoint
In two rounds one and two months after extracorporeal lithotripsy

Method of measurement
Ultrasound and CT scan

Intervention groups

1

Description
Intervention group: Supine Positions in Percutaneous Nephrolithotomy

Category
Treatment - Surgery

2

Description
Intervention group: Prone Positions in Percutaneous Nephrolithotomy

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
Tehran University of Medical Sciences

Full name of responsible person
Dr. Akbar Fotouhi

Street address
Sixth Floor, Central University, Quds Ave., Keshavarz Boulevard, Tehran, Iran.

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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
Dr Mohammad Kazem Aghamir

Position
Head of Urology Research Center

Latest degree
Specialist

Other areas of specialty/work
Urology

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Person responsible for updating data

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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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