

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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)

Phone

+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

Contact**Name of organization / entity**

Tehran University of Medical Sciences

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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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

-

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

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