Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A Comparison Between Minimally invasive Surgery Ureterolithotomy and Trans urethral Lithotripsy with Retrograde Internal Surgery

Protocol summary

Study aim
A Comparison Between Minimally invasive Surgery Ureterolithotomy and Trans urethral Lithotripsy with Retrograde Internal Surgery

Design
A clinical trial with two groups of patients: parallel, therapeutic, blanced block randomization, single blind (patient). 74 patients referred to Sinai Hospital.

Settings and conduct
74 patients at Sina Hospital. blanced block randomization, single blind(patient). Patients are divided into two groups: Group 1: Minimally invasive Surgery Ureterolithotomy. Group 2 : Trans urethral Lithotripsy with Retrograde Internal Surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Consent to participate in the study. 2- Urinary stones larger than 15 mm. Exclusion criteria: 1-Patients affected by hemorrhagic diseases. 2- Cases that have Systemic Inflammatory Response Syndrome. 3- Untreated urinary tract infection.

Intervention groups
Intervention group 1: Minimally invasive Surgery Ureterolithotomy. Intervention group 2 : Trans urethral Lithotripsy with Retrograde Internal Surgery.

Main outcome variables
Complications, hospitalization time, surgical time, and success rate of complete stone therapy.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190624043991N12**
Registration date: **2020-11-28, 1399/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-28, 1399/09/08**
Update count: **0**

Registration date
2020-11-28, 1399/09/08

Registrant information

Name
Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6634 8560

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mkaghamir@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-05, 1399/05/15

Expected recruitment end date
2021-06-05, 1400/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A Comparison Between Minimally invasive Surgery Ureterolithotomy and Trans urethral Lithotripsy with Retrograde Internal Surgery

Public title
Minimally invasive Surgery Ureterolithotomy and Trans urethral Lithotripsy with Retrograde Internal Surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study Urinary stones larger than 15 mm

Exclusion criteria:

Patients affected by hemorrhagic diseases Cases that have Systemic Inflammatory Response Syndrome untreated urinary tract infection

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a single-blind randomized clinical trial. For randomization, the blanced 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 sealdenvelop 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 (Minimally invasive Surgery Ureterolithotomy) or (Trans urethral Lithotripsy with Retrograde Internal Surgery) group based on the randomly selected envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients who have given their consent to participate in the study will be treated with Minimally invasive Surgery Ureterolithotomy or Trans urethral Lithotripsy with Retrograde Internal Surgery. The patient has no information about the surgical procedure and the design.

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

2020-08-03, 1399/05/13

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.298

Health conditions studied

1

Description of health condition studied

Urethral stone

ICD-10 code

N21

ICD-10 code description

Calculus of lower urinary tract

Primary outcomes

1

Description

Treatment of urinary stones(Kidney stones)

Timepoint

before and one month after surgery

Method of measurement

Spiral CT scan of the abdomen and pelvis, before and after surgery

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Minimally invasive Surgery Ureterolithotomy

Category

Treatment - Surgery

2

Description

Intervention group: Trans urethral Lithotripsy with Retrograde Internal Surgery

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Dr seyed mohammad kazaem aghamir mohammadali
Street address
Urology Research Center, Sina Hospital, Imam Khomeini 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. Mohammad Ali Sahraian
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Sixth Floor,Central University,Quds Ave., Keshavarz Boulevard, Tehran.
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Web page address
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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
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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