

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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)

Phone

+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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Web page address<http://sinahospital.tums.ac.ir>**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<http://vcr.tums.ac.ir/>**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

Molecular Medicine

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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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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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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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