

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 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

###### Email address

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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mkaghamir@tums.ac.ir

**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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**Latest degree**  
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**Other areas of specialty/work**  
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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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