

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 2026

### Investigating the effect of antibiotics in washing fluid on inflammatory factors during and after transurethral lithotripsy: a single blind clinical trial

#### Protocol summary

##### Study aim

Investigating the effect of antibiotics in washing fluid on inflammatory factors during and after transurethral lithotripsy: a single blind clinical trial

##### Design

The study is interventional in two control groups (40 people) and intervention (40 people), single-blind, phase 3, parallel and therapeutic.

##### Settings and conduct

This clinical trial will be conducted in Sinai Hospital, Urology Research Center, on 80 patients. Group A: - Control group: 0.9% standard saline serum B: Intervention group: 1000 mg ceftriaxone antibiotic + 6 liters of 0.9% normal saline.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness and informed consent of the patient, age between 20 and 70 years, elective surgery, stones smaller than 20 mm in the upper middle ureter. Exclusion criteria: previous history of urinary system surgery, concurrent kidney stones, bilateral ureteral stones, anatomical disorders, positive urine culture before surgery, use of corticosteroids or antibiotics before surgery, immunodeficiency, diabetes

##### Intervention groups

Control group: normal saline serum 0.9% Intervention group: 1000 mg ceftriaxone antibiotic + 6 liters of normal saline 0.9%

##### Main outcome variables

Reducing the possibility of post-surgery infections, treatment costs, morbidity, and mortality due to this surgery and no effect on the gastrointestinal microbiome.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190624043991N20**

Registration date: **2023-09-25, 1402/07/03**

Registration timing: **prospective**

Last update: **2023-09-25, 1402/07/03**

Update count: **0**

#### Registration date

2023-09-25, 1402/07/03

#### 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

2024-02-09, 1402/11/20

#### Expected recruitment end date

2025-02-08, 1403/11/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Investigating the effect of antibiotics in washing fluid on inflammatory factors during and after transurethral

lithotripsy: a single blind clinical trial

## Public title

Antibiotic effect during and after intra-organ stone crushing

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients in the study and obtaining informed consent aged between 20 and 70 years elective surgery stones smaller than 20 million meters located in the upper lower ureter in CTS without contrast.

### Exclusion criteria:

Previous history of urinary system surgery Having simultaneous kidney stones Having anatomical or functional kidney disorders Bilateral ureteral stones Positive urine culture before surgery Use of corticosteroids or antibiotics before surgery Immunodeficiency Taking drugs Causes of immunodeficiency Any active or chronic infection during the last three months Diabetes

## Age

From **20 years** old to **70 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

80 study participants who meet the entry requirements will be randomly split into two equal groups of 40 participants. The randomization method of separate blocks is used to create quadruple blocks for randomization. The first patient's chosen illness will be assigned to the "first group," and the second patient will be assigned to the "second group". Patients are divided into two groups: 1-control group: 0.9% normal saline serum and 2-intervention group: 1000 mg of ceftriaxone antibiotic + 6 liters of 0.9% normal saline.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The present study is a single-blind, randomized clinical trial study. The patient or participant will not know how to be placed in the control or intervention groups.

## Placebo

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

2023-01-15, 1401/10/25

#### Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1402.020

## Health conditions studied

### 1

#### Description of health condition studied

Urinary tract infection

#### ICD-10 code

N39.0

#### ICD-10 code description

Urinary tract infection, site not specified

## Primary outcomes

### 1

#### Description

The effect of antibiotics in the lavage fluid on the occurrence of infections during and after intra-organ stone crushing

#### Timepoint

6-12 hours after surgery

#### Method of measurement

Laboratory diagnosis (urine culture and inflammatory markers)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: 1000 mg ceftriaxone antibiotic + 6 liters of normal saline 0.9%. they receive

#### Category

Treatment - Drugs

## 2

### Description

Control group: control group: normal saline serum 0.9

### Category

Treatment - Drugs

## 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

##### City

Tehran

##### Province

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##### Postal code

1136746911

##### Phone

+98 21 6634 8500

##### Fax

+98 21 6634 8553

##### Email

mkaghamir@tums.ac.ir

##### Web page address

<http://urc.tums.ac.ir>

## 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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##### Postal code

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+98 21 8163 3685

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+98 21 8163 3686

##### Email

vcr@tums.ac.ir

##### Web page address

<http://vcr.tums.ac.ir/>

##### Grant name

##### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

No

### 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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mirzaee.scholar@gmail.com

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<https://URC@tums.ac.ir>

## 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

##### Street address

Urology Research Center- Sina Hospital - Imam  
Khomeini St

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## 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**

Medical Biology

**Street address**

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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**

En Researchers working in academia, physicians, surgeons and hospitals

**Under which criteria data/document could be used**

En 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**

En 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**