

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

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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

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Sixth Floor, Central University, Quds Ave., Keshavarz
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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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Person responsible for scientific inquiries

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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

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