

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of prophylactic antibiotics before intraureteral lithotripsy on infection and inflammatory factors

Protocol summary

Study aim

Effect of prophylactic antibiotics before intraureteral lithotripsy on infection and inflammatory factors

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 80 patients. The rand function of Excel software was used for randomization.

Settings and conduct

In this double-blind clinical trial study, all non-febrile hospitalized patients with ureteral stones with negative preoperative culture in Shahid Beheshti Hospital of Babol are included in the study. One hour before surgery, the first group (intervention group) is given an intravenous dose of cefazolin 1gr (from the pharmaceutical company Aria). To the second group (control group) 1 hour before surgery, placebo, which is normal saline serum, is given. The placebo will be designed similar to cefazolin. After selecting and randomizing, patients will be divided into a and b groups. The participants and those who will evaluate outcome, will not be informed how to patients allocated in groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All non-febrile hospitalized patients with ureteral stones with negative preoperative culture are included in the study. Exclusion criteria: age older than 65 years, heavy smoking, chronic steroid use, immunodeficiency

Intervention groups

For the case group, 1 gram of cefazolin antibiotic is used one hour before the operation, and for the control group and for the control group, 1 hour before the operation, a placebo, which is normal saline, is given.

Main outcome variables

Infection, Fever

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221127056624N1**

Registration date: **2022-12-04, 1401/09/13**

Registration timing: **prospective**

Last update: **2022-12-04, 1401/09/13**

Update count: **0**

Registration date

2022-12-04, 1401/09/13

Registrant information

Name

Abazar Akbarzadeh pasha

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 3222 6285

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-15, 1401/09/24

Expected recruitment end date

2023-02-13, 1401/11/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of prophylactic antibiotics before intraureteral lithotripsy on infection and inflammatory factors

Public title

The effect of preoperative antibiotic prophylaxis in ureteral stone crushing surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All non-febrile hospitalized patients with negative preoperative cultures have ureteral stones

Exclusion criteria:

Age more than 65 years Heavy smoker (more than 25 cigarettes per day) Chronic steroid use Immunodeficiency Extracorporeal catheters Simultaneous infection of other parts of the body Long-term hospitalization

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

After applying the entry and exit criteria, subjects will be randomly assigned using permutation blocks. By using Sealedenvelop.com software, a sequence of size 80 will be produced. The randomization unit is an individual. The size of the blocks is 4 and in each block each intervention group will be repeated twice (the randomization ratio in each block is 1:1). Using this randomly generated list, the participants are assigned to one of the two study groups. In order to hide the list of random allocation, a special code will be assigned to each of the intervention groups, which even the main implementer of the project (supervisor) is not aware of. These codes are written on a paper and placed inside a sealed envelope. A unique code specific to each patient will be written on this paper and its envelope. All envelopes will be placed in a larger box in random order and sealed in the box. The main researcher, after reviewing the criteria for entering the study and obtaining informed consent, as well as registering the patient's profile in a special form, in collaboration with the random allocation list (this person is an expert, other than the main researcher, who is involved in the patient recruitment process and sample entry) is called and randomization of that patient is done.

Blinding (investigator's opinion)

Double blinded

Blinding description

After selection and randomization, patients will be divided into groups a and b. The form of the drugs is completely the same, so the patient will not know the

type of intervention. The participants and those who will assess the outcome will not know how the patients are arranged in the groups. Therefore, the study will be conducted in a double-blind manner.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

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4716681451

Approval date

2022-10-30, 1401/08/08

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.165

Health conditions studied

1

Description of health condition studied

Ureteral stone

ICD-10 code

N20.1

ICD-10 code description

Calculus of ureter

Primary outcomes

1

Description

Assessing the patient's fever with a thermometer

Timepoint

72 hours after surgery

Method of measurement

With a thermometer

2

Description

Evaluation of bacteriuria based on urinalysis and urine

culture

Timepoint

72 hours after surgery and one week and one month after surgery

Method of measurement

Evaluation of urinalysis and urine culture

Secondary outcomes**1****Description**

Examination of urine culture

Timepoint

72 hours after surgery and one week and one month after surgery

Method of measurement

Urine culture test

2**Description**

Urinalysis test

Timepoint

72 hours after surgery and one week and one month after surgery

Method of measurement

Urinalysis test

Intervention groups**1****Description**

Intervention group: Intravenous antibiotic cefazolin with a dose of 1 gram (obtained from Aria Pharmaceutical Company) will be given intravenously half to one hour before the operation and two doses (1 gram) after the operation at an interval of 6 hours.

Category

Treatment - Drugs

2**Description**

Control group: They will receive 10 cc of normal isotonic saline (placebo) half to an hour before the operation and two doses after the operation at an interval of 6 hours, intravenously. The placebo will be designed to look similar to cefazolin.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

Full name of responsible person

Dr. Abazar Akbarzadeh Pasha

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr. Omid Majidian

Position

Resident

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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Latest degree

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Other areas of specialty/work

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Latest degree

Specialist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD**Study Protocol**

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available