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

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Iran (Islamic Republic of)

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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
City
Babol
Province
Mazandaran
Postal code
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
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Specialist
Other areas of specialty/work
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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