Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparing the effectiveness of Ciprofloxacin, Ceftriaxone, and Gentamicin for preventing bacteriuria after transurethral lithotripsy (TUL)

Protocol summary

Study aim
Comparison of the Effectiveness of ciprofloxacin, ceftriaxone, and gentamicin for preventing of bacteriuria , febrile urinary tract infection and systemic inflammatory response syndrome after transurethral lithotripsy

Design
single-blind randomized controlled trial

Settings and conduct
the first group, 88 patients use 1 g ceftriaxone 30 minutes before surgery. In the second group, 88 patients are injected with 400mg ciprofloxacin 30 minutes before surgery. And in the third group, 88 patients are injected 2 mg/kg gentamicin 30 minutes before surgery. In Shahid Rahmon Hospital, Yazd

Participants/Inclusion and exclusion criteria
Inclusion criteria 1. Patients with middle and distal ureteral calculi with negetive urine culture that are going to undergo TUL (the maximum diameter of the stone is <2 cm) 2. Age 18 to 65 years old. Exlusion criteria 1. Asymptomatic patients with colony count ≥ 10 5 CFU/mL or a symptomatic UTI with colony count ≥ 10 3 CFU/mL 2. Patients with any catheter. 3. Patients with preoperative fever (body temperature ≥ 38°C). 4. Patients with a history of diabetes. 5. Patients with immunocompromised diseases or using immunosuppressive drugs. 6. Patients with abnormal renal function. 7. Patients who have received antimicrobial treatment within two weeks before enrollment. 8. Pregnant or breastfeeding women. 9. Patients who are allergic to our research drugs.

Intervention groups
The enrolled patients are randomly divided into 3 different antibiotics groups according to the random number table. The patients are randomly allocated, using a randomization ratio of 1:1:1.

Main outcome variables
Determining the most effective prophylactic antibiotic for TUL with the lowest bacteriuria , fUTI and SIRS after it

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231031059918N1**
Registration date: **2023-11-13, 1402/08/22**
Registration timing: **prospective**

Last update: **2023-11-13, 1402/08/22**
Update count: **0**

Registration date
2023-11-13, 1402/08/22

Registrant information

Name
nazanin akhavan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3523 6600

Email address
nazanin1379akhavan@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-25, 1402/09/04

Expected recruitment end date
2024-11-24, 1403/09/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effectiveness of Ciprofloxacin, Ceftriaxone, and Gentamicin for preventing bacteriuria after transurethral lithotripsy (TUL)

Public title

Comparing the effectiveness of Ciprofloxacin, Ceftriaxone, and Gentamicin for preventing bacteriuria after transurethral lithotripsy (TUL)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with middle and distal ureteral calculi with negetive urine culture that are going to undergo TUL (the maximum diameter of the stone is <2 cm) Age 18 to 65 years old.

Exclusion criteria:

Asymptomatic patients with colony count ≥ 10 5 CFU/mL or a symptomatic UTI with colony count ≥ 10 3 CFU/mL Patients with any catheter. Patients with preoperative fever (body temperature ≥ 38°C) Patients with a history of diabetes. Patients with immunocompromised diseases or using immunosuppressive drugs Patients with abnormal renal function Patients who have received antimicrobial treatment within two weeks before enrollment Pregnant or breastfeeding women Patients who are allergic to our research drugs.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **264**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocating the samples to the intervention groups will be through the creation of a random sequence using the permutation block method using the Random Allocation software and a computer-generated list of random numbers. Therefore it is done by a person not involved in the study and randomized codes are kept in sealed envelopes and open at the time of patient recruitment .

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will not know which of the 3 antibiotics they will receive. However, Principal investigator, health care personnel and data collection officer will be informed.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Medicine - Shahid Sadougi University of Medical Sciences, Yazd (Research Ethics Committee

Street address

Jomhouri Boulevard, Alley 56, Seventh Alley, Second Dead End, Second House

City

yazd

Province

Yazd

Postal code

8917956195

Approval date

2023-11-08, 1402/08/17

Ethics committee reference number

IR.SSU.MEDICINE.REC.1402.229

Health conditions studied

1

Description of health condition studied

Comparing the effectiveness of ciprofloxacin, ceftriaxone, and gentamicin for preventing bacteriuria after transurethral lithotripsy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Significant bacteriuria was defined asymptomatic patients with colony count ≥ 10 5 CFU/mL or a symptomatic UTI with colony count ≥ 10 3 CFU/mL.

Timepoint

After 48 hour of surgery, routine urine tests and urine bacterial cultures, will be recorded.

Method of measurement

Routine urine tests and urine bacteria culture are done in the Rahnemoun hospital laboratory.

2

Description

Febrile urinary tract infection (fUTI) is defined as a body temperature of 38.5 C accompanying urinary tract infection after surgery.

Timepoint

After 48 hour of surgery

Method of measurement

body temperature by thermometer will be recorded.

3

Description
• SIRS criteria defined by: WBC < 4000 or > 12000 , heart rate > 90 per minute , temperature < 36 C or > 38 C , respiratory rate >20 or pCO2 < 32 . (Presence of two or more of these criteria is accepted as SIRS.)
Timepoint
After 48 hour of surgery
Method of measurement
Routine urine tests and urine bacteria culture are done in the Rahnemoun hospital laboratory.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 88 patients use 1 g ceftriaxone 30 minutes before surgery
Category
Treatment - Drugs

2

Description
Intervention group: 88 patients are injected with 400mg ciprofloxacin 30 minutes before surgery.
Category
Treatment - Drugs

3

Description
Intervention group: 88 patients are injected 2 mg/kg gentamicin 30 minutes before surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Mohammad Ali Rahnamoun Hospital
Full name of responsible person
nazanin akhavan
Street address
Shahid Beheshti Square, Farrokhi Street, Emergency Alley
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
nazanin akhavan
Street address
Yazd-square Alam-Bulvar Shohada Anohom-Shahid Sadougi University of Medical Sciences Campus-Yazd Faculty of Medicine
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891515173143
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info@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
nazanin Akhavan
Position
medical stager
Latest degree
A Level or less
Other areas of specialty/work
Urology / Infectious disease
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts after the results are printed
To whom data/document is available
all of the people
Under which criteria data/document could be used
There is no special condition
From where data/document is obtainable
My postal address for correspondence, or email address, phone numbers
What processes are involved for a request to access data/document
There is no specific process
Comments