Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of prophylactic effect of single-dose and continuous-dose antibiotics on urinary tract infections (UTI) in patients with Double-J ureteral stent following transurethral lithotripsy (TUL)

Protocol summary

Study aim
Determination of the safety of omitting continuous antibiotic treatment in patients with Double-J ureteral stent following transurethral lithotripsy (TUL) and stenting

Design
Randomized clinical trial, with control group, parallel groups, phase 2-3 study on 90 patients, block randomization with blocks of size 4 with a ratio of 1 to 1 via a online program named sealed envelop/randomisation

Settings and conduct
The study will be performed in the urology ward and operating room of Razi Hospital in Rasht. This study is randomly performed on 90 patients in parallel groups. Patients in intervention group will receive single dose intravenous ciprofloxacin (400 mg) before starting the procedure. Patients in control group, in addition to antibiotics prophylaxis, will receive 1 tablet of ciprofloxacin (500 mg) every 12 hours for 3 days and then one tablet of ciprofloxacin (250 mg) every night until stent removal.

Participants/Inclusion and exclusion criteria
Inclusion criteria: have a sterile urine culture before stent placement; Exclusion criteria: use of antibiotics during the 2 weeks before the stent insertion, history of prostate and bladder cancer, Recurrent urinary tract infections, pregnancy

Intervention groups
Intervention group: receiving single dose intravenous ciprofloxacin (400 mg) before procedure; Control group: receiving single dose intravenous ciprofloxacin (400 mg) before procedure + receiving one tablet of ciprofloxacin (500 mg) every 12 hours for 3 days and then one tablet of ciprofloxacin (250 mg) every night until stent removal

Main outcome variables
Urinary tract infection, fever and stent-related symptoms

General information

Reason for update
More clear explanation of the type of intervention and correction of the type of consequences as well as some typographical errors

Acronym

IRCT registration information
IRCT registration number: **IRCT20220213054009N1**
Registration date: **2022-04-18, 1401/01/29**
Registration timing: **prospective**

Last update: **2023-02-13, 1401/11/24**
Update count: **1**

Registration date
2022-04-18, 1401/01/29

Registrant information

Name
Reza Shahrokhi Damavand

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
2022-05-21, 1401/02/31

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prophylactic effect of single-dose and continuous-dose antibiotics on urinary tract infections (UTI) in patients with Double-J ureteral stent following transurethral lithotripsy (TUL)

Public title

Comparison of prophylactic effect of single-dose and continuous-dose antibiotics on urinary tract infections (UTI) following transurethral lithotripsy (TUL) and stenting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Have a sterile urine culture before stent placement

Exclusion criteria:

Fever Use of antibiotics during the 2 weeks before the stenting operation Purulent discharge during TUL History or treatment of obstructive symptoms Chronic bacterial prostatitis Chronic pelvic pain syndrome Prostate cancer Chronic ureteral obstruction Obstruction due to malignancy Iatrogenic trauma Conditions prone to bleeding History of bladder cancer Recurrent urinary tract infections Irritable bladder syndrome History of mental or neurological disease Taking alpha-blockers and anticholinergics, painkillers, or other medications that may interfere with the symptoms of ureteral stent Pregnancy

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will done with blocks of size 4 with a ratio of 1 to 1 (as two groups A and B) via a online program named sealed envelop/randomization. One of the researcher (resident of urology) based on a table prepared from four random blocks, assigns patients to two groups: A (single dose) and B (continuous), by random replacement method.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

Sardar Jangal street

City

Rasht

Province

Guilan

Postal code

41448-95655

Approval date

2022-01-26, 1400/11/06

Ethics committee reference number

IR.GUMS.REC.1400.523

Health conditions studied

1

Description of health condition studied

Post-operative urinary tract infection

ICD-10 code

T83.51

ICD-10 code description

Infection and inflammatory reaction due to urinary catheter

Primary outcomes

1

Description

Urinary tract infection after inserting the stent

Timepoint

The mean duration of stent indwelling time and before removing the stent

Method of measurement

Urine culture and urinalysis

2

Description

Fever

Timepoint

During the stent indwelling time

Method of measurement

Interview and physical exam

3

Description

Hematuria

Timepoint
During of stent indwelling time and before removing the stent
Method of measurement
Interview and questionnaire

4

Description
Dysuria
Timepoint
During of stent indwelling time and before removing the stent
Method of measurement
Interview and questionnaire

5

Description
Frequency
Timepoint
During of stent indwelling time and before removing the stent
Method of measurement
Interview and questionnaire

6

Description
Nocturia
Timepoint
During of stent indwelling time and before removing the stent
Method of measurement
Interview and questionnaire

7

Description
Flank pain
Timepoint
During of stent indwelling time and before removing the stent
Method of measurement
Interview and questionnaire

Secondary outcomes

1

Description
Side effects of contentious antibiotics
Timepoint
During of stent indwelling time
Method of measurement
Interview

Intervention groups

1

Description
Intervention group: receiving single dose intravenous ciprofloxacin (400 mg) before procedure
Category
Treatment - Drugs

2

Description
Control group:receiving single dose intravenous ciprofloxacin (400 mg) before procedure + receiving 1 tablet of ciprofloxacin (500 mg) every 12 hours for 3 days and then one tablet of ciprofloxacin (250 mg) every night until stent removal
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Reza Shahrokhi Damavand
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Sponsors / Funding sources

1

Sponsor
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Web page address
https://urc.gums.ac.ir/
Grant name
10506
Grant code / Reference number
32
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urology Research Center, Guilan 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
Rasht University of Medical Sciences
Full name of responsible person
Bahador Heidari Bateni
Position
Resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available