Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of safety of omitting antibiotic prophylaxis prior to Transurethral Lithotripsy (TUL) in two groups of patients with and without positive urine culture referred to Razi Hospital in Rasht: a pilot study

Protocol summary

Study aim

Determination of the safety of omitting prophylactic antibiotic therapy prior to Transurethral Lithotripsy (TUL) in two groups of patients with and without positive urine culture

Design

Non-randomized controlled trial study, by available gradual and sequential sampling method, with a sample size of 50 patients

Settings and conduct

The study will be performed in the urology ward and operating room of Razi Hospital in Rasht. This pilot study is performed on 50 patients gradually and sequentially. Patients will be divided into two groups based on the result of urine culture: A (positive preoperative urine culture) and B (negative preoperative urine culture). Intraoperative prophylactic antibiotics are prescribed in all patients undergoing Transurethral Lithotripsy (TUL).

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 15 years and under 65 years, patient consent to participate in the study Exclusion criteria: Patients with symptoms of upper urinary tract infection; Use of preoperative antibiotics; Drug abuse; Patients with single kidney and uncontrolled systemic diseases.

Intervention groups

Intervention group: Omitting antibiotic prior to Transurethral Lithotripsy (TUL) in patients with positive urine culture; Control group: Patients without positive urine culture in whom antibiotic is not prescribed as standard prior to Transurethral Lithotripsy (TUL)

Main outcome variables

Postoperative fever, urinary tract infection and complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090427001853N17**
Registration date: **2021-10-24, 1400/08/02**
Registration timing: **prospective**

Last update: **2021-10-24, 1400/08/02**
Update count: **0**

Registration date

2021-10-24, 1400/08/02

Registrant information

Name
Siavash Falahatkar

Name of organization / entity
Urology Research Center

Country
Iran (Islamic Republic of)

Phone
+98 13 3352 5259

Email address
urc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-31, 1400/08/09

Expected recruitment end date

2022-04-29, 1401/02/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of safety of omitting antibiotic prophylaxis prior to Transurethral Lithotripsy (TUL) in two groups of patients with and without positive urine culture referred to Razi Hospital in Rasht: a pilot study

Public title
Safety of omitting antibiotic prophylaxis prior to Transurethral Lithotripsy (TUL)
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with lower and middle ureteral stones who are candidates for Transurethral Lithotripsy (TUL) Age between 15 and 65 years Patient consent to participate in the study
Exclusion criteria:
Upper urinary tract infection based on symptoms of fever, shivering, flank pain and leukocytosis Use of preoperative antibiotics Drug abuse Patients with single kidney Uncontrolled systemic diseases
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
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
2021-09-01, 1400/06/10
Ethics committee reference number
IR.GUMS.REC.1400.250

Health conditions studied

1

Description of health condition studied
Postoperative complication
ICD-10 code
N99.89
ICD-10 code description
Other postprocedural complications and disorders of genitourinary system

Primary outcomes

1

Description
Postoperative fever
Timepoint
After the operation until the time of discharge
Method of measurement
Examination

2

Description
Postoperative urinary tract infection
Timepoint
48 hours after surgery
Method of measurement
Urine culture

3

Description
Postoperative complications
Timepoint
After the operation until the time of discharge
Method of measurement
Examination and laboratory tests

Secondary outcomes

1

Description
Success rate (stone free rate)
Timepoint
1 month after surgery
Method of measurement
Sonography, CT-scan

2

Description
Operation time
Timepoint
From start to recovery
Method of measurement
Stopwatch

3

Description
Hospital stay
Timepoint
On the day of discharge
Method of measurement
Hospitalization days

4

Description
Analgesic use
Timepoint
After surgery, during the period of hospitalization
Method of measurement
Question from the patient, examination

5

Description
Readmission
Timepoint
Up to one month after surgery
Method of measurement
Question from the patient

Intervention groups

1

Description
Intervention group: Omitting prophylactic antibiotic therapy prior to Transurethral Lithotripsy (TUL) in patients with positive urine culture in whom routinely antibiotics are continued until urine culture become negative
Category
Other

2

Description
Control group: Patients without positive urine culture in whom antibiotic is not prescribed as standard prior to Transurethral Lithotripsy (TUL)
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Siavash Falahatkar
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Sponsors / Funding sources

1

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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
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Reza Falahatkar
Position
Medical student
Latest degree
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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