

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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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Sardar-e-Jangal street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urology Research Center, Guilan University of Medical Sciences

Full name of responsible person

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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

Full name of responsible person

Reza Falahatkar

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Position

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Specialist

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Non-faculty researcher

Latest degree

Master

Other areas of specialty/work

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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