

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effectiveness of cefazolin prophylaxis on infection after TUL surgery

Protocol summary

Study aim

The effectiveness of cefazolin prophylaxis on infection after TUL surgery

Design

A single-blind clinical trial with interventional and control groups using placebo based on randomized whit random-numbered table.

Settings and conduct

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. 48-72 hours before giving cefazolin or placebo to each group, we examine body temperature (T), urine culture (U / C), and urine analysis (U / A) of patients. Patients who lack bacteriuria and fever and have negative urine culture are studied and otherwise excluded from the study. 24 hours after the TUL surgery, U / A, U / C and body temperature (T) will be re-established and re-determined. We will evaluate the results by statistical analysis before and after the operation, and thus we will examine the efficacy of cefazolin prophylaxis.

Participants/Inclusion and exclusion criteria

All patients with ureter stone who need transureteral lithotripsy (TUL) and are satisfied. patients don't have ureteral stent, don't have urethral catheter, don't have bacteriuria, have negative urine culture before TUL, have no immune deficiency.

Intervention groups

1. A group that receives prophylaxis antibiotics (cephazolin). 2. A group that receives placebo.

Main outcome variables

urine culture urine analysis body temperature

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160514027893N2**

Registration date: **2018-10-08, 1397/07/16**

Registration timing: **prospective**

Last update: **2018-10-08, 1397/07/16**

Update count: **0**

Registration date

2018-10-08, 1397/07/16

Registrant information

Name

Ramin Haghighi

Name of organization / entity

North Khorasan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 58 3272 4475

Email address

haghighi.ramin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of cefazolin prophylaxis on infection after TUL surgery

Public title

effect of cefazolin prophylaxis in TUL surgery

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with ureter stone who need transureteral lithotripsy (TUL) and are satisfied.

Exclusion criteria:

Patients who don't have ureteral stent or urethral catheter. Patients who don't have bacteriuria. Negative urine culture before TUL. No immune deficiency.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups of intervention and control by random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

After selecting and randomizing, patients will be divided into a and b groups. The surgeon, statistical analyzer and those who will evaluate outcome, will not be informed how to patients allocated in groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of North Khorasan University of Medical Sciences

Street address

medical School.Shahriar Ave.Bojnord.North Khorasan.Iran

City

bojnord

Province

North Khorasan

Postal code

9453155174

Approval date

2018-05-15, 1397/02/25

Ethics committee reference number

IR.NKUMS.REC.1397.016

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

Evaluation of bacteriuria based on urine culture and urine analysis

Timepoint

24 hours after TUL surgery

Method of measurement

Evaluation of urine analysis and urine culture

Secondary outcomes

1

Description

Evaluation of patient fever with thermometer

Timepoint

24 hours after TUL surgery

Method of measurement

With thermometer

2

Description

Evaluation of urinary culture

Timepoint

24 hours after TUL surgery

Method of measurement

Urine culture test

3

Description

Urinalysis test

Timepoint

24 hours after TUL surgery

Method of measurement

Urinalysis test

Intervention groups

1

Description

Intervention group: A group that receives prophylaxis antibiotics. Cefazolin is given at a dose of 1gr (intravenous) from Aria Pharmaceutical Company.

Category

Prevention

2

Description

Control group: A group that receives placebo (normal saline). Normal saline serum from Samen Pharmaceutical Company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hasan Hospital

Full name of responsible person

Ramin Haghighi

Street address

Esfarayen Road, 4 km of Arkan, Imam Hasan Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Amirhosein Khoshi

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Ahmad Kameli

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for updating data**Contact****Name of organization / entity**

Bojnourd University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

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Esfarayen Road, 4 km of Arkan, Imam Hasan Hospital

City

Bojnourd

Province**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

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

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