Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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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
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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
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Esfarayen Road, 4 km of Arkan, Imam Hasan Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Ahmad Kameli
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Instructor
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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
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