Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

A comparative study on the effects of prevention antibiotics cefixime and levofloxacin on infections after urinary tract dilatation in patients with recurrent stenosis

Protocol summary

Study aim
A comparative study of the therapeutic effects of two antibiotics Cefixime and Levofloxacin in preventing and improving infections after urethral dilatation.

Design
Clinical trial with Control group, Parallel groups, single blind, Phase 3, 50 Patients, table of random numbers used for allocation

Settings and conduct
The present study is a double blind randomized clinical trial that was performed on 50 patients referred to the urology clinic of Ghaem Hospital due to urethral stricture from April of 2021 to the June 2022. Eligible patients were randomly divided into two groups after obtaining informed consent. The intervention group (25 people) before and after urethral dilatation in given 500mg Levofloxacin for 3 days (one dose before urethral dilatation and two doses after urethral dilatation).The control group (25 people) before and after urethral dilatation in given 400mg cefixime for 3 days (one dose before urethral dilatation and two doses after urethral dilatation).Demographic information (age, occupation, etc.), pain during the procedure and (VAS),PVR,The rate of improvement of urinary retention symptoms, side effects of drugs and U/A,U/C,Cr were collected in a checklist

Participants/Inclusion and exclusion criteria
Inclusion criteria: single stricture and less than 1.5 cm in length urethral stricture; single urethral strictures are less than 2 cm; patients over 18 years old; no history of liver and kidney problems. Exclusion criteria: history of sensitivity to the two mentioned drugs; the patient's unwillingness to continue participation in the study.

Intervention groups
The intervention group (25 people) before and after urethral dilatation in given 500mg Levofloxacin for 3 days. The control group (25 people) before and after urethral dilatation in given 400mg Cefixime for 3 days

Main outcome variables
Side effects of drugs and lab data U/A,U/C,Cr

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220711055433N2**
Registration date: **2022-10-27, 1401/08/05**
Registration timing: **retrospective**

Last update: **2022-10-27, 1401/08/05**
Update count: **0**

Registration date
2022-10-27, 1401/08/05

Registrant information

Name
Amir Abbas Asadpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3843 2256

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-06, 1399/10/17

Expected recruitment end date
2022-01-07, 1400/10/17

Actual recruitment start date
2021-01-06, 1399/10/17

Actual recruitment end date
2022-06-21, 1401/03/31
Trial completion date
2025-09-22, 1404/06/31

Scientific title
A comparative study on the effects of prevention antibiotics cefixime and levofloxacin on infections after urinary tract dilatation in patients with recurrent stenosis

Public title
Comparative cefixime and levofloxacin on infections after urinary tract dilatation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Single urethral stricture and stricture length less than 2 cm Strictures shorter than 1.5 cm in the anterior urethra Age older than 18 years old
Exclusion criteria:
Patient refusal of participation History of allergy to levofloxacin and cefixime
Age
From **18 years** old
Gender
Male

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The generation of random numbers using random blocks and the envelope method is such that the envelopes will be prepared by a member of the research team and random numbers with the help of random blocks, printed and placed inside the envelope. The lid of the envelopes will be closed and its contents will not be visible from the outside. Then the person takes an envelope and enters the intervention or control group based on the contents of the envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
The evaluator and the analyst unaware of the intervention and control groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ghoreshi Building, Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2019-09-03, 1398/06/12
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.573

Health conditions studied

1

Description of health condition studied
Urethral Stricture
ICD-10 code
N35.9
ICD-10 code description
Urethral stricture, unspecified

Primary outcomes

1

Description
Urinary tract infections after urethral dilatation
Timepoint
The rate of improvement in urinary tract infection in the first, second and third months after dilatation
Method of measurement
The use of Urine analysis and Urine culture

Secondary outcomes

1

Description
Side effects caused by cefixime or levofloxacin
Timepoint
72 hours after urethral dilatation
Method of measurement
Medical records

Intervention groups

1

Description
Intervention group: Before and after urethral dilatation, a

500mg tablet of levofloxacin is given for 3 days (one dose before urethral dilatation and two doses after urethral dilatation).

Category

Treatment - Drugs

2

Description

Control group: Before and after urethral dilatation, a tablet cefixime 400 mg is given for 3 days (one dose before urethral dilatation and two doses after urethral dilatation).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem Hospital

Full name of responsible person
Amir Abbas Asadpour

Street address
Ghaem Hospital, Ahmadabad Blvd.

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b.ghaem@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Majid Ghayor Mobarhan

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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

Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Amir Abbas Asadpour

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Urology

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Urology Department, 3rd floor, Ghaem Hospital, Ahmadabad Blvd

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Person responsible for scientific inquiries

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Full name of responsible person
Amir Abbas Asadpour

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available