

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 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)

Phone

+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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9176699199

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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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Person responsible for scientific 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

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Person responsible for updating data

Contact

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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