

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the role of antibiotics in urinary tract infections after ESWL Lithotripsy in patients with the indication of Lithotripsy

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Evaluation of the role of antibiotics in urinary tract infections after ESWL Lithotripsy in patients with the indication of Lithotripsy

Last update: **2020-08-14, 1399/05/24**

Update count: **0**

Registration date

2020-08-14, 1399/05/24

Design

98 patients with urinary tract stones who had ESWL indication with negative urine culture before ESWL were included in the study. After randomization, patients were divided into two groups. The first group, patients were treated with cefixime 400 mg daily for half an hour before ESWL and also for one week after ESWL, and the control group was given only single-dose antibiotics after ESWL. Finally, urine culture was taken from all patients 14 days after the procedure.

Registrant information

Name

Mahdi Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3372 5581

Email address

dr.m.mohammadi50@gmail.com

Settings and conduct

Bushehr University of Medical Sciences, litholapaxy department of urology clinic

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion in the study: Presence of urinary tract stones, indication for ESWL, referral to urology clinic Exclusion: Non-native patients, dissatisfaction with participation in the study, positive urine culture, relative contraindications

Expected recruitment start date

2020-08-05, 1399/05/15

Expected recruitment end date

2020-08-20, 1399/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

The first group, which was the case group, patients were treated with cefixime 400 mg daily for half an hour before ESWL and also for one week after ESWL, and the control group was given only single-dose antibiotics after ESWL.

Main outcome variables

Prevention and reduction of infection after ESWL .

Scientific title

Evaluation of the role of antibiotics in urinary tract infections after ESWL Lithotripsy in patients with the indication of Lithotripsy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200725048205N1**

Registration date: **2020-08-14, 1399/05/24**

Public title

Role of antibiotics in urinary tract infection prevention after lithotripsy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Existence of urinary system stones Indication of doing ESWL Refer to the urology clinic

Exclusion criteria:

Non-native patients Dissatisfaction with participation in the study Positive urinary culture Existence of relative contraindications

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 98

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: individual Patients are selected based on randomization with even and odd numbers method. Patients whose last medical record number is even are in the control group and patients whose last number is odd are in the treatment group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Bushehr University of Medical Sciences

Street address

Bushehr Province, Bandar Bushehr, Kuy-e-Bandar, Moallem St

City

Bushehr

Province

Boushehr

Postal code

7514633341

Approval date

2020-06-14, 1399/03/25

Ethics committee reference number

IR.BPUMS.REC.1399.049

Health conditions studied

1

Description of health condition studied

Patients with kidney stones

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

Reduction of urinary tract infection after ESWL

Timepoint

14 days after the end of the test period

Method of measurement

Urine culture

Secondary outcomes

empty

Intervention groups

1

Description

Control group: The control group is given a single dose of Cefsexime 400 mg after ESWL treatment.

Category

Prevention

2

Description

Intervention group: Patients were treated with cefixime 400 mg daily for half an hour before ESWL and also for one week after ESWL.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Persina Gulf Martyrs Hospital, Bushehr

Full name of responsible person

Mehdi Honarkar Ramezani

Street address

Bushehr - Taleghani St. - Persian Gulf Martyrs Medical Center

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MPGH@BPUMS.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Gholamreza Khamisipour

Street address

Bushehr, Bahmani, Salman Farsi St., Medical Sciences
Campus, First Floor

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Research@Bpums.Ac.Ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Mehdi Honarkar Ramezani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

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

Title and more details about the data/document

After finishing all the data collected from the people in the study is published.

When the data will become available and for how long

The access period will start one month after the results are published.

To whom data/document is available

Everyone connected to the university and the health system will have access.

Under which criteria data/document could be used

To use and study the results of this study, people who desire visiting the Central Library or the person responsible for the act of Bushehr University of Medical Sciences.

From where data/document is obtainable

Bushehr University of Medical Sciences Central Library

What processes are involved for a request to access data/document

Visit and present an ID card

Comments