

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of antibiotic prophylaxis during extracorporeal shock wave lithotripsy(ESWL) in prevention of urinary tract infections in patients with urine proven sterile prior to treatment

Protocol summary

Summary

In this double blind prospective clinical trial, all patients with kidney stones and ureteral lithotripsy attended to the Babol Clinic 2014-2015 were enrolled. Inclusion criteria: minimum age 18 years, negative urine culture before ESWL; absence of Foley catheter or nephrostomy tube; no history of infectious stones. Exclusion criteria: patients who have not had suitable follow up; those who have done urine culture in the 2 weeks after ESWL; manipulation of the urinary system during and after ESWL. Patients are divided into two groups of A and B. Group A will be given 200 mg of Ofloxacin every 12 hours, preferably after surgery for up to 3 days and group B will be given placebo which is a pill made from flour. Then in all patients, 5 days before crusher surgery, urine culture will be done. Two weeks after ESWL, urine culture and ultrasound will be done and the information will be collected. Variables include size of the stones, the number and location of the stone, the Double j over the crusher. First variables will be given, including the amount of wave energy and crushed stone (immediately after ESWL) in the final stage of gathering information. Then we will check the following variables: the amount of crushed stone, the presence of renal colic after ESWL (response to oral pain medications and intravenous), the remaining stones larger than 5 mm ultrasound controls, urine culture results (presence of a colony of 105 ml / CFU to culture is seen as positive), urinary tract infection symptoms, frequency and urgency with positive culture, urinary sepsis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062422897N1**
Registration date: **2015-11-25, 1394/09/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-25, 1394/09/04

Registrant information

Name

masomeh bayani

Name of organization / entity

medical university of babol

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8284

Email address

m_baiany@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of Babol University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of antibiotic prophylaxis during extracorporeal shock wave lithotripsy(ESWL) in prevention of urinary tract infections in patients with urine proven sterile prior

to treatment

Public title

Efficacy of antibiotic prophylaxis during extracorporeal shock wave lithotripsy in prevention of urinary tract infections in patients with urine proven sterile prior to treatment

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: minimum age 18 years; negative urine culture before ESWL; absence of Foley catheter or nephrostomy tube; no history of infectious stones. Exclusion criteria: patients who have not had suitable follow up; those who have done urine culture in the 2 weeks after ESWL; manipulation of the urinary system during and after ESWL.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Rohani Hospital

City

Babol

Postal code

47176-41367

Approval date

2015-06-07, 1394/03/17

Ethics committee reference number

MUBABOL.REC.1394.30

Health conditions studied

1

Description of health condition studied

UTI

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

The incidence of urinary tract infections was measured among patients without risk factors.

Timepoint

Urine analysis was performed 5 days before ESWL surgery.

Method of measurement

Calculate number organisms in the urine according to CFU.

Secondary outcomes

1

Description

Increased antibiotic resistance and drug side effects and interactions compared with placebo has occurred.

Timepoint

monthly

Method of measurement

Urine culture and physical examination

Intervention groups

1

Description

Patients are divided into two groups of A and B. Group A (the intervention group) will be given 200 mg of Ofloxacin every 12 hours.

Category

Treatment - Drugs

2

Description

Group B (control group) will be given placebo which is a pill made from flour.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Private Babol Clinic Hospital
Full name of responsible person
Dr.Hamid Shafie
Street address
Babol University of Medical Sciences- Medicine faculty
City
Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Hamid Shafie
Street address
Babol University of Medical Sciences, Gangafrouz
street, Daneshgah squer
City
Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Hamid Shafie
Position
Urology specialist
Other areas of specialty/work
Street address
Babol University of Medical Sciences, Gangafrouz
street, Daneshgah squer
City
Babol
Postal code
Phone
+98 11 3219 2832
Fax
Email

dr_hamidshafi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Masomeh Bayani
Position
Infectious specialist
Other areas of specialty/work
Street address
Babol University of Medical Sciences, Gangafrouz
street, Daneshgah squer
City
babol
Postal code
4717641367
Phone
+98 11 3219 2832
Fax
+98 11 3219 2832
Email
m_baiany@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Masomeh Ilkhani
Position
Medical students
Other areas of specialty/work
Street address
Babol University of Medical Sciences, Gangafrouz
street, Daneshgah squer
City
Babol
Postal code
Phone
00
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty