

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing effect of tamsulosin drug and Lithorex B on renal colic and the expulsion of renal stone and urinary stones after extracorporeal shock wave lithotripsy (ESWL)

Protocol summary

Summary

Background: Our aim was to compare oral tamsulosin and Lithorex B for treatment of renal colic and stone passage after extracorporeal shockwave lithotripsy (ESWL) Methods: In this randomized clinical trial from March 2014-2016 sixty four (64) patients with renal and upper ureteral stones with size less than 20 millimeter that referred to Shahid Beheshti Hospital of Yasuj after taking informed consent form and approval of ethics committee are divided into two groups by simple sampling method. In all patients completed history and physical exam was done and basal serum samples was checked. Patients who have coagulopathy; active infection; azotemia; uncontrolled hypertension; hypersensitivity to narcotic or analgesic drugs and pregnant women were excluded. Then in both groups extracorporeal shockwave lithotripsy was done. Then patients were observed for two hours and if patient have no complication, they will be allocated in two groups. In both groups it has been offered that patients should drink 10-12 glasses of water every day. In first group one tablet of Lithorex B was prescribed by one glass of water every 8 hour. In the second group a capsule of tamsulosin was prescribed with one glass of water every night. Two weeks later patients were visited again and KUB or ultrasonography was done and efficacy of treatment according to change in the size of stone and the existence of residual stones were measured and recorded. The pain intensity of patients' before and after ESWL and during taking drugs measured and recorded by means of visual analog scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606151323N10**

Registration date: **2016-08-28, 1395/06/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 6070

Email address

dr.mehrabi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research vice chancellor, Yasuj University of Medical Sciences,

Expected recruitment start date

2014-03-01, 1392/12/10

Expected recruitment end date

2016-03-01, 1394/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of tamsulosin drug and Lithorex B on renal colic and the expulsion of renal stone and urinary

stones after extracorporeal shock wave lithotripsy (ESWL)

Public title

tamsulosin versus Lithorex B on renal colic and the expulsion of urinary stones after extracorporeal shock wave lithotripsy (ESWL)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age more than 15 years old suffering from renal or upper ureteral stone; stone size less than 20 millimeter. Having informed consent form Exclusion criteria: presence of coagulopathy; presence of active infection; presence of azotemia; uncontrolled hypertension; hypersensitivity to narcotic or analgesic drugs; pregnancy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 64

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran

City

Yasuj

Postal code

Approval date

2015-03-06, 1393/12/15

Ethics committee reference number

1088/2/23/پ

Health conditions studied

1

Description of health condition studied

Calculus of kidney and ureter

ICD-10 code

N20.2

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

Crushing of renal and upper ureteral stones less than 20milimeter

Timepoint

Two weeks after the lithotripsy and treatment

Method of measurement

KUB and Ultrasonography and report of patients

Secondary outcomes

1

Description

pain intensity before and after ESWL and during treatment

Timepoint

daily to two weeks after ESWL

Method of measurement

Visual analoge scale

Intervention groups

1

Description

In first group after Extra corporeal shockwave lithotripsy(ESWL) one tablet of Lithorex B was prescribed by one glass of water every 8 hour for two weeks.

Category

Treatment - Drugs

2

Description

In second group after Extra corporeal shockwave lithotripsy(ESWL) one capsule of tamsulosin 0.4 milligram was prescribed by one glass of water every night for two weeks.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shaheed Beheshti hospital

Full name of responsible person

Sadrollah Mehrabi

Street address

Shaheed Beheshti hospital, Montazeri street, Yasuj

City

Yasuj

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research vice chancellor , Yasuj University of Medical Sciences

Full name of responsible person

Mehdi Akbartabar

Street address

Mottahari street, Research vice chancellor, Yasuj University of Medical Sciences, , Yasuj, Iran

City

Yasuj

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research vice chancellor , Yasuj 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**

Faculty of Medicine, Yasuj University of Medical Sciences

Full name of responsible person

Sadrollah Mehrabi

Position

professor, Fellowship of endourology and laparoscopy

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Professor of urology department, Fellowship of endourology and laparoscopy

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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