Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 Beheshi 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
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Mottahari street,Research vice chancelor, 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
Other areas of specialty/work
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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