

# 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 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

**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

**Other areas of specialty/work****Street address**

No.22, Bahonar street, Yasuj, Iran

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+98 74 3334 6070

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Faculty of medicine, Yasuj University of Medical Sciences

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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*