# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 Nov 2026

## comparison the efficacy of tamsulosin and hydrophilic extract of Allium Jesdianum versus tamsulosin in treatment of renal colic and passage of urinary stones after Extracorporeal shock wave lithotripsy (ESWL)

## Protocol summary

**Study aim**
comparison the efficacy of oral tamsulosin and hydrophilic extract of allium Jesdianum versus tamsulosin for treatment of renal colic and stone passage after extracorporeal shock wave lithotripsy (ESWL)

**Design**
In this randomized clinical trial from March to December 2018 with simple sampling methods eighty (80) patients older than 18 years old suffering from renal or ureteral stones less than 20 millimeter allocated in one of two groups.

**Settings and conduct**
Patients referring to ESWL unit of Shahid Beheshti hospital of Yasuj after performing ESWL by standard method and taking informed consent form entered the study.

**Participants/Inclusion and exclusion criteria**
patients older than 18 years old with renal and upper ureteral stones with diameter less than 20 millimeter candidate for ESWL and after taking informed consent form and approval of ethics committee will be entered the study.

**Intervention groups**
In first group one capsule of tamsulosin 0.4 mg will be prescribed with one glass of water every night. In the second group 1 gram of extract in the form of capsule will be prescribed in 2 divided doses with one glass of water every 12 hour with one capsule of tamsulosin 0.4 mg every night for two weeks.

**Main outcome variables**
efficacy of treatment according to change in the size of stone and passage of stones by KUB and ultrasonography , decreasing patients' pain intensity before and after ESWL and during taking drugs according to visual analog scale .

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20081011001323N16**
Registration date: **2018-04-04, 1397/01/15**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-04, 1397/01/15**
Update count: **0**

**Registration date**
2018-04-04, 1397/01/15

**Registrant information**

**Name**
Sadrollah Mehrabi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 74 3334 6070

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**
Research vice chancellor , Yasuj University of Medical Sciences

**Expected recruitment start date**
2018-03-21, 1397/01/01

**Expected recruitment end date**
2018-10-23, 1397/08/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
comparison the efficacy of tamsulosin and hydrophilic extract of Allium Jesdianum versus tamsulosin in treatment of renal colic and passage of urinary stones after Extracorporeal shock wave lithotripsy (ESWL)

**Public title**
comparison of tamsulosin and Allium Jesdianum in treatment of renal colic and passage of urinary stones

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
age more than 18 years old suffering from renal or upper ureteral stone less than 20 millimeter Having informed consent form

**Exclusion criteria:**
presence of active infection drugs azotemia uncontrolled coagulopathy uncontrolled pregnancy hypertension severe cardiovascular disorders hypersensitivity to chemical or herbal drugs

**Age**
From **18 years** old to **99 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **80**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Randomized allocation with simple sampling method to intervention and controlled groups

**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 Yasuj University of Medical Sciences

**Street address**
Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran

**City**
Yasuj

**Province**
Kohgilouyeh-va-Boyrahmad

**Postal code**
7591741417

**Approval date**
2018-03-12, 1396/12/21

**Ethics committee reference number**
IR.YUMS.REC.1396.183

## 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 calculus of ureter

## Primary outcomes

### 1

**Description**
Passage of renal and upper ureteral stones less than 20milimeter after ESWL and receiving treatment

**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**
visit and examinatin and check by visual analogue scale

## Intervention groups

### 1

**Description**
In first group after Extra corporeal shock wave lithotripsy(ESWL) one capsule of tamsulosin 0.4 milligram will be prescribed by one glass of water every night for two weeks.

**Category**
Treatment - Drugs

**2**

**Description**
in second group 1 gram of allium jesdianum extract in the form of capsule every 12 hour with one capsule of tamsulosin 0.4 milligram every night with one glass of water will be prescribed 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
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Shaheed Beheshi hospital, Montazeri street, Yasuj,Iran
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Yasouj University of Medical Sciences
**Full name of responsible person**
Dr Ali Mousavizadeh
**Street address**
Mottahari street,Research vice chancelor, Yasuj University of Medical Sciences, , Iran
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+98 74 3334 6074
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health.epid@gmail.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Yasouj 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**
Faculty of Medicine,Yasuj University of Medical Sciences
**Full name of responsible person**
Sadrollah Mehrabi
**Position**
professor, Fellowship of endourology and laparoscopy
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Urology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be 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