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)

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+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
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
Street address
Shaheed Beheshi hospital, Montazeri street, Yasuj,Iran
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dr.mehrabi@yums.ac.ir

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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7591741417
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+98 74 3334 6074
Email
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