

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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 20millimeter 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 Beheshti hospital, Montazeri street,
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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

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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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Name of organization / entity

Faculty of medicine,Yasuj University of Medical
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Other areas of specialty/work
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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