

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the efficacy of oral Pejanum harmala seeds and tamsulosin on pain improvement and expulsion of renal and ureteral stones sized 6-10 millimeter in patients older than 18 years old

#### Protocol summary

##### Study aim

Comparison of the efficacy of oral Pejanum harmala seeds and tamsulosin on pain improvement and expulsion of renal and ureteral stones sized 6-10 millimeter in patients older than 18 years old

##### Design

In this randomized, parallel group clinical trial from March 2018 to February 2019 with simple sampling methods eighty (80) patients older than 18 years old allocated in one of two groups and will received intervention for two weeks. .

##### Settings and conduct

Patients referring to Shahid Mofateh clinic of Yasuj suffering from renal or ureteral stones 5-10 millimeter with simple sampling method allocated in one of two groups. The history and physical exam and basic serum samples will be checked . In two groups it is recommended to walk and do exercise at least 30 minutes per day .One and three months later, the patients will be re-examined and KUB or ultrasonography would be performed and the success the treatment was measured and recorded according to the size of the stone and the presence of remaining gems. Also pain severity of patients will be checked and recorded by Visual analogue scale(VAS) during treatment and two weeks after that.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients older than 18 years old with kidney and ureteral stones sized 6- 10 mm , taking informed consent form , approval of the ethics committee of university Exclusion criteria: Patients with coagulopathy, pregnant ladies and those that have history of herbal or medicinal allergy .

##### Intervention groups

Intervention group: Pejanum Harmala seeds will be provided in form of capsule and prescribe in dosage of 50 m/kg(milligram/kilogram) per day single dose with

one glass of water for two weeks. Control group: Tamsulosin capsule .4 mg will prescribed every night with one glass of water for two weeks.

##### Main outcome variables

Change in the size and passage of stones ; pain severity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20081011001323N17**

Registration date: **2018-06-25, 1397/04/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-25, 1397/04/04**

Update count: **0**

##### Registration date

2018-06-25, 1397/04/04

##### 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

##### Expected recruitment start date

2018-03-21, 1397/01/01

##### Expected recruitment end date

2019-02-20, 1397/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the efficacy of oral Pejanum harmala seeds and tamsulosin on pain improvement and expulsion of renal and ureteral stones sized 6-10 millimeter in patients older than 18 years old

**Public title**

Efficacy of Pejanum harmala seeds and tamsulosin on renal and ureteral stones

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

age more than 18 years old suffering from renal or upper ureteral stone less than 10 millimeter Having informed consent form

**Exclusion criteria:**

Uncontrolled coagulopathy Azotemia Pregnancy Presence of active urinary tract infection Allergy to medical or herbal drugs Severe cardiovascular or pulmonary disease

**Age**

From 18 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**

Patients are allocated with simple sampling methods and random numbering table to one of each group and received the intervention of that group.

**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-Boyrhmad

**Postal code**

7591741417

**Approval date**

2018-03-11, 1396/12/20

**Ethics committee reference number**

IR.YUMS.REC.1396.120

**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 with calculus of ureter

**Primary outcomes****1****Description**

Passage of renal and upper ureteral stones sized 5-10 millimeter

**Timepoint**

Two weeks and one month after start of treatment

**Method of measurement**

Taking KUB and Ultrasonography and report of patients

**2****Description**

Pain severity score due to passage of stones

**Timepoint**

During study and two weeks and one month after start of treatment

**Method of measurement**

With Visual Analogue Scale(VAS)

**Secondary outcomes****1****Description**

development of side effects

**Timepoint**

from start of treatment to one month later

**Method of measurement**

according to history and physical exam and patient report

## Intervention groups

### 1

#### Description

Intervention group: Pejanum Harmala seeds in form of capsule and prescribed in dosage of 50 m/kg(milligram/kilogram) per day single dose with one glass of water for two weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Tamsulosin capsule .4 mg prescribed every night with one glass of water for two weeks.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Mofateh clinic

##### Full name of responsible person

Sadrolleh Mehrabi

##### Street address

No.22 , Shahid Madani street, Bahonar Blvd, Yasuj, Iran

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591951176

##### Phone

+98 74 3322 9297

##### Email

sadrollahm@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Dr Ali Mousavizadeh

##### Street address

Vice chancellor for Research, Yasuj University of Medical Sciences, Mottahari Street, Yasuj, Iran

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591741417

##### Phone

+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

Yasouj University of Medical Sciences

##### Full name of responsible person

Sadrollah Mehrabi

##### Position

Professor Education vice chancellor, Yasuj University of Medical Sciences

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Urology

##### Street address

Vice chancellor for Education, Yasuj University of Medical Sciences, Mottahari Street, Yasuj, Iran

##### City

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##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591541417

##### Phone

+98 74 3334 6070

##### Email

dr.mehrabi@yums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Yasouj 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 updating data****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Sadrollah Mehrabi

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professor, Fellowship of endourology and laparoscopy

**Latest degree**

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**Email**

dr.mehrabi@yums.ac.ir

**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