

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-Boyerahmad

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

Yasuj

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

Street address

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

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

+98 74 3334 6070

Email

dr.mehrabi@yums.ac.ir

Person responsible for updating data**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

Street address

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

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

+98 74 3334 6070

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