Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of the efficacy of oral Pejanum harmala seeds and tamsulosin on pain improvement and expulsion of renal and ureteral stones sized6-10 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 sized6-10 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 than18 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 tableto 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-Boyrahmad
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
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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
Vice chancellor for Research, Yasuj University of Medical Sciences, Mottahari Street, Yasuj, 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
Yasouj University of Medical Sciences
Full name of responsible person
Sadrollah Mehrabi
Position
Professor Education vice chansellor, Yasuj University of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Urology
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Person responsible for scientific inquiries

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Yasouj University of Medical Sciences
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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

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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