Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison effect of combined Malva sylvestis and leaf of Allium canadanse with tamsulosin on pain improvement and passage of ureteral stones less than 10 millimeters in patients older than 18 years old

Protocol summary

Study aim

Comparison of the efficacy of Malva sylvestis and leaf of Allium canadanse and tamsulosin on pain improvement and passage of 4 to 10 mm ureteral stones in adult patients over 18 years of age

Design

In this randomized, parallel group clinical trial from March to December 2019 with simple sampling methods eighty (80) patients older than 18 years old are 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 ureteral stones 4-10 millimeter randomly allocated with simple random allocation method in one of two groups (Malva sylvestis and Allium canadanse or tamsulosin). The basic serum samples are checked in all patients. In two groups it is recommended to walk and do exercise at least 30 minutes per day .Two weeks and one month later, the patients are re-examined and KUB or ultrasonography is performed and the success of treatment will measured according to the size of stone and the presence of residual stones. Pain severity of patients are checked and recorded by Visual analogue scale (VAS) during treatment and two weeks later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients older than 18 years old with ureteral stones with sizes of 4- 10 mm, taking informed consent form, Exclusion criteria: Patients with coagulation disorders, pregnant women and those with a history of herbal or medicinal allergy.

Intervention groups

Intervention group: Powder of Malva sylvestis and leaf of Allium canadanse is provided in form of capsule and prescribe in dosage of 10 mg/kg per day in three divided doses after meal with one glass of water for two weeks. Control group: Tamsulosin capsule 0.4 mg will prescribe 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: **IRCT20081011001323N22**
Registration date: **2019-05-01, 1398/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-01, 1398/02/11**
Update count: **0**

Registration date

2019-05-01, 1398/02/11

Registrant information

Name
Sadrollah Mehrabi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-12-31, 1398/10/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison effect of combined Malva sylvestis and leaf of Allium canadanse with tamsulosin on pain improvement and passage of ureteral stones less than 10 millimeters in patients older than 18 years old

Public title
Effect of combined Allium canadanse and Malva sylvestis in Comparison with tamsulosin in urinary stones
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age more than18 years old Suffering from 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 Suffering from cardiovascular or pulmonary disease Suffering from hepatic disease
Age
From **18 years** old to **99 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are allocated randomly with simple random allocation method by use of random number table to one of each group (Allium canadanse and Malva sylvestis or tamsulosin) 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
7591741414
Approval date
2019-03-02, 1397/12/11
Ethics committee reference number
IR.YUMS.REC.1397.150

Health conditions studied

1

Description of health condition studied
ureteral stones
ICD-10 code
N20.1
ICD-10 code description
Calculus of ureter

Primary outcomes

1

Description
passage of ureteral stones with sizes from 4 to 10 millimeters
Timepoint
Two weeks and one month after start of treatment
Method of measurement
Perform KUB and sonography and patient report

Secondary outcomes

1

Description
The severity of pain due to stone passage
Timepoint
During the study , two weeks and one month after starting treatment
Method of measurement
With Visual Analogue Scale (VAS)

Intervention groups

1

Description
Intervention group: combined Malva sylvestis and leaf of Allium canadanse is produced in form of capsule and is consumed at a dose of 10 mg / kg / day (divided in two doses) after meal with a glass of water for 2 weeks. Also it is recommended that patients walk and do exercise at least 30 minutes per day.

Category
Treatment - Drugs

2

Description
Control group: Tamsulosin capsule 0.4 mg day is prescribed with a glass of water every night for two weeks.Also it is recommended that patients walk and do exercise at least 30 minutes per day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mofateh clinic of Yasuj
Full name of responsible person
Sadrolleh Mehrabi
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Sponsors / Funding sources

1

Sponsor
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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
Yasouj University of Medical Sciences
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Professor, Education vice chancellor, Yasuj University of Medical Sciences
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Subspecialist
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available