

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison effect of combined Malva sylvestis and leaf of Allium canadense 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 canadense 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 canadense 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 canadense 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

Country

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 canadense 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 canadense and Malva sylvestis in Comparison with tamsulosin in urinary stones

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age more than 18 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 canadense 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

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Yasuj University of Medical Sciences, Mottahari srteet, Yasuj, Iran

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Kohgilouyeh-va-Boyrahmad

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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 canadense 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****Name of organization / entity**

Yasouj University of Medical Sciences

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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

Full name of responsible person

Yasouj University of Medical Sciences

Position

Professor, Education vice chancellor, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Person responsible for updating data

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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