

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of the efficacy of allium sativum and tamsulosin on pain improvement and expulsion rate of 4 to 10 mm kidney and ureteral stones in adult patients over 18 years of age

Protocol summary

Study aim

Comparison of the efficacy of allium sativum and tamsulosin on pain improvement and removal of 4 to 10 mm kidney and ureteral stones in adult patients over 18 years of age

Design

In this randomized, parallel group clinical trial from October 2018 to October 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 4-10 millimeter allocated in one of two groups with simple sampling method. 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 .Two weeks and one month later, the patients will be re-examined and KUB or ultrasonography would be performed and the success of treatment was measured and recorded according to the size of the stone and the presence of residual stones. 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 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: Fresh allium sativum will be provided in form of capsule and prescribe in dosage of 40 m/kg (milligram/kilogram) 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: **IRCT20081011001323N20**

Registration date: **2018-11-21, 1397/08/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-21, 1397/08/30**

Update count: **0**

Registration date

2018-11-21, 1397/08/30

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

2018-11-11, 1397/08/20

Expected recruitment end date

2019-11-11, 1398/08/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of allium sativum and tamsulosin on pain improvement and expulsion rate of 4 to 10 mm kidney and ureteral stones in adult patients over 18 years of age

Public title
Allium sativum and oral tamsulosin on pain improvement and expulsion of urinary stones

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age more than 18 years old Suffering from renal or 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 severe cardiovascular or pulmonary 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 with simple sampling methods and random numbering table to one of each group (allium sativum 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

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Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Approval date

2018-11-03, 1397/08/12

Ethics committee reference number

IR.YUMS.REC.1397.101

Health conditions studied

1

Description of health condition studied

Renal and ureteral calculus

ICD-10 code

N20.2

ICD-10 code description

Calculus of kidney with calculus of ureter

Primary outcomes

1

Description

passage of renal and 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: fresh allium sativum is produced in form of capsule and is consumed at a dose of 40 mg / kg / day (divided into three doses) after meal with a glass of water for 2 weeks.

Category

Treatment - Drugs

2**Description**

Control group: Tamsulosin capsule 4 mg / day is prescribed with a glass of water every night for two weeks.

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

Full name of responsible person

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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

Sadrollah Mehrabi

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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Full name of responsible person

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Latest degree

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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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more 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