Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison efficacy of zea mays and tamsulosin on pain improvement and expulsion of renal and ureteral stones sized 4-10 millimeter

Protocol summary

Study aim

Comparison efficacy of zea mays and tamsulosin on pain improvement and expulsion of renal and ureteral stones sized 4-10 millimeter

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 (zea mays or tamsulosin) and will received intervention for two weeks.

Settings and conduct

Patients referring to Shahid Mofateh clinic of Yasuj suffering from renal or ureteral stones with sizes of 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:Age more than18 years old suffering from renal or ureteral stone less than 10 millimeter, having informed consent form Exclusion criteria:Uncontrolled coagulopathy , Pregnancy, Azotemia, Allergy to medical or herbal drugs, Severe cardiovascular or pulmonary disease

Intervention groups

Intervention group: zea mays will be provided in form of capsule and will prescribe in dosage of 20 m/kg (milligram/kilogram) per day 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: **IRCT20081011001323N19**
Registration date: **2018-11-15, 1397/08/24**
Registration timing: **prospective**

Last update: **2018-11-15, 1397/08/24**
Update count: **0**

Registration date

2018-11-15, 1397/08/24

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

2018-11-22, 1397/09/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison efficacy of zea mays and tamsulosin on pain improvement and expulsion of renal and ureteral stones sized 4-10 millimeter

Public title
Efficacy of zea mays and tamsulosin on urinary stones

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age more than18 years old Suffering from renal or ureteral stone less than 10 millimeter Having informed consent form

Exclusion criteria:
Uncontrolled coagulopathy Pregnancy Azotemia Allergy to medical or herbal drugs 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 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
2018-11-03, 1397/08/12

Ethics committee reference number
IR.YUMS.REC.1397.100

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 with sizes from 4-10 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

empty

Intervention groups

1

Description
Intervention group: Zea mays in form of capsule will prepare and prescribed in dosage of 20m/kg (milligram/kilogram) per day after meal with one glass of water 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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Shahid Mofateh clinic, Montazeri street,Yasuj

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

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Person responsible for scientific inquiries

Contact

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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)
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