Clinical Trial Protocol
Iranian Registry of Clinical Trials
01 Mar 2022

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
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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
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

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591741417

Approval date
2018-11-03, 1397/08/12

Ethics committee reference number
IR.YUMS.REC.1397.101

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
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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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Position
Professor, Education vice chancellor, Yasuj University of Medical Sciences
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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