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
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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

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

**Recruitment centers**

1

**Recruitment center**
- **Name of recruitment center**: Shahid Mofateh clinic of Yasuj
- **Full name of responsible person**: Sadrollah Mehrabi
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**Sponsors / Funding sources**

1

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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**: Domestic

**Type of organization providing the funding**: Academic

**Person responsible for general inquiries**

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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