Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison effect of Nigella sativa and tamsulosin on pain improvement and passage of renal and ureteral stones sized 4-10 millimeter

Protocol summary

Study aim

Comparison effect of Nigella sativa and tamsulosin on pain improvement and passage of renal and ureteral stones sized 4-10 millimeter

Design

In this non blinded randomized parallel clinical trial, 80 Patients are allocated randomly with simple sequential allocation in one of the two groups (Nigella sativa or tamsulosin) by help of sealed envelope and will receive the intervention of that group.

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. the first group will received Tamsulosin 0.4 mg per night and second group will received Nigella sativa capsule in dose of 300 mg three times per day for two weeks. 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 radiography or ultrasonography will be performed and the success of treatment will measure according to the size of the stone and the presence of residual stones. 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 Exclusion criteria:Uncontrolled coagulopathy , Pregnancy, Azotemia, Allergy to medical or herbal drugs

Intervention groups

Intervention group: Nigella sativa (produced by Salamat Zagros Company) will be provided in form of capsule and will prescribe in divided dosage of 15mg/kg (milligram/kilogram) per day after meal with one glass of water for two weeks. Control group: Tamsulosin capsule 0.4 mg (produced by Abidi Company) 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: **IRCT20081011001323N23**
Registration date: **2019-05-03, 1398/02/13**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-03, 1398/02/13**
Update count: **0**

Registration date

2019-05-03, 1398/02/13

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

2019-02-09, 1397/11/20

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison effect of Nigella sativa and tamsulosin on pain improvement and passage of renal and ureteral stones sized 4-10 millimeter

Public title
Effect of Nigella sativa 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 randomly with simple sequential allocation in one of the two study groups (Nigella sativa or tamsulosin) by help of sealed envelope and receive the intervention of the same group. The unit of randomization will be the referred patient. In every envelope, one of two codes (A=Nigella sativa) and or (B=tamsulosin) will be taken. The sealed envelopes will be placed at the disposal of the expert. With the referral of each patient one of the envelopes will be randomly selected by the patients and will be introduced as a study group. The stratification approach is not used. Concealment will not take place in the study.

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
2019-03-09, 1397/12/18

Ethics committee reference number
IR.YUMS.REC.1397.155

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(kidney,ureter and bladder) 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: Nigella sativa in form of capsule(produced by Salamat Zagros company) will prepare and prescribed in divided dosage of 15mg/kg (milligram/kilogram) per day after meal with one glass of water for two weeks.
Category
Treatment - Drugs

2

Description
Control group: Tamsulosin capsule 0.4 mg (produced by Abidi Company) will prescribe every night 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
Street address
Shahid Mofateh clinic, Montazeri street,Yasuj
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Phone
+98 74 3322 4721
Fax
+98 74 3333 1814
Email
mofatehclinic@yasooj.ir

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
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Phone
+98 74 3334 6074
Email
health.epid@gmail.com
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, Chairman of Urology Department, Yasuj University of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Urology
Street address
Yasuj University of Medical Sciences, Mottahari Street, Yasuj, Iran
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Phone
+98 33346070
Email
dr.mehrabi@yums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Sadrollah Mehrabi
Position
Professor, Fellowship of endourology and laparoscopy
Latest degree

Subspecialist

Other areas of specialty/work
Urology

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

City
Yasuj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591741417

Phone
+98 74 3334 6070

Email
dr.mehrabi@yums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Yasouj University of Medical Sciences

Full name of responsible person
Sadrollah Mehrabi

Position
Professor, Fellowship of endourology and laparoscopy

Latest degree
Subspecialist

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Urology

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

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Postal code
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Phone
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Email
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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