

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Change in the size and passage of stones ; pain severity

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

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 than 18 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-Boyerahmad

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-Boyerahmad

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

Other areas of specialty/work

Urology

Street address

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

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Phone

+98 74 3334 6070

Email

dr.mehrabi@yums.ac.ir

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