

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison effect of a combined extract of black seed and *Urtica dioica* with tamsulosin on pain improvement and expulsion of ureteral stones sized 5-10 millimeter in patients older than 18 years old

Protocol summary

Study aim

Comparison effect of a combined extract of *Nigella sativa* and *Urtica dioica* with tamsulosin on pain improvement and passage of ureteral stones sized 5-10 millimeter in 18 years old patients

Design

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

Settings and conduct

Patients referring to Shahid Mofateh clinic of Yasuj suffering from ureteral stones with sizes of 5-10 millimeters allocated in one of two groups. the first group will receive Tamsulosin 0.4 mg per night and the second group will receive a combined extract of *Nigella sativa*(480 mg) and *Urtica dioica*(180 mg) capsule per day for two weeks. Two weeks and one month later, the patients will be re-examined and ultrasonography will be performed and the success of the treatment will measure according to the size of the stone. pain severity of patients will be checked and recorded by Visual analog scale (VAS) during treatment and two weeks after that.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age more than 18 years old suffering from ureteral stone sized 5-10 millimeter Exclusion criteria: Uncontrolled coagulopathy, Pregnancy, Azotemia, Allergy to medical or herbal drugs

Intervention groups

Intervention group: combined extract of *Nigella sativa* and *Urtica dioica*(produced by Salamat Zagros Company) will be provided in form of a capsule and will prescribe with a dosage of 600 milligrams 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: **IRCT20081011001323N27**

Registration date: **2021-06-19, 1400/03/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-19, 1400/03/29**

Update count: **0**

Registration date

2021-06-19, 1400/03/29

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

2021-06-01, 1400/03/11

Expected recruitment end date

2022-06-01, 1401/03/11

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison effect of a combined extract of black seed and Urtica dioica with tamsulosin on pain improvement and expulsion of ureteral stones sized 5-10 millimeter in patients older than 18 years old

Public title
Comparison effect of black seed and Urtica dioica with tamsulosin in the treatment of ureteral stones

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age more than 18 years old Suffering from 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 cardiovascular or pulmonary disease Suffering from hepatic disease Suffering from peptic ulcer 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 a simple random allocation method by use of a random number table to one of each group (combined Black seed and Urtica dioica 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-Boyerahmad
Postal code
7591741414
Approval date
2021-05-19, 1400/02/29
Ethics committee reference number
IR.YUMS.REC.1400.028

Health conditions studied

1

Description of health condition studied
ureteral stones
ICD-10 code
N20.1
ICD-10 code description
Calculus of ureter

Primary outcomes

1

Description
passage of ureteral stones with sizes from 5 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: combined extract of Black seed and leaf of Urtica dioica (120 mg of Urtica dioica and 120 mg

of Black seed) is produced in form of a capsule and is consumed (divided into two doses) after the meal with a glass of water for 2 weeks. Also, it is recommended that patients walk and do exercise at least 30 minutes per day.

Category

Treatment - Drugs

2**Description**

Control group: Tamsulosin capsule 0.4 mg day is prescribed with a glass of water every night for two weeks. Also it is recommended that patients walk and do exercise at least 30 minutes per day.

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**

Yasuj University of Medical Sciences

Full name of responsible person

Ali Mousavizadeh

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Deputy of research, Yasuj University of Medical Sciences,, Motahari St

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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

Yasuj 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**

Yasuj University of Medical Sciences

Full name of responsible person

Sadrolleh Mehrabi

Position

Professor, Director of Urology Departement, Yasuj University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yasuj 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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sadrollah Mehrabi

Position

Professor, Fellowship of endourology and laparoscopy

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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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