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 than18 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 than18 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 than18 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 than18 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-Boyrahmad

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
Yasouj University of Medical Sciences

Full name of responsible person
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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

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

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Position
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Latest degree
Subspecialist

Other areas of specialty/work
Urology

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Person responsible for updating data

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Other areas of specialty/work
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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