Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study the effect of the product contains Black Seed on the bigger stones or equal to five millimetres in patients with kidney stones without metabolic or infectious risk factors.

Protocol summary

Study aim

The purpose of this study was to investigate the effect of Nigella sativa on kidney stone dissolving.

Design

In this research, 60 eligible patients with a history of kidney stone equal or larger than to 5 mm diameter on kidney ultrasonography were randomly divided into two groups of control and intervention. Group allocation was concealed by assigning a unique code to each participant.

Settings and conduct

We designed a randomized, double arm, double blind, placebo-controlled clinical trial. This study was carried out in urology clinic of Ghaem and Imam Reza Hospital, affiliated to Mashhad University of Medical Sciences, Iran, from November 2015 to May 2016.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Men and women aged 20 to 60 years, people 20-60 years old with kidney stone disease that has been confirmed by ultrasound sonography. They should have kidney stones equal or larger than 5 mm. Exclusion criteria : Breast feeding, pregnancy, any renal disorder which requires new treatment protocols and known allergy to black seed.

Intervention groups

Eligible patients were divided into two groups. Patients were randomly assigned to receive either a 10 weeks black seed capsules (500 mg 2 times per day) as the intervention group, or placebo capsules (500 mg 2 times per day) as the control group.

Main outcome variables

The primary outcome measure in this trial was change in the size of renal stones by using ultrasound sonography. Secondary outcome measures were changes in the levels of serum calcium and urine PH.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160619028530N2**
Registration date: **2018-02-20, 1396/12/01**
Registration timing: **retrospective**

Last update: **2018-02-20, 1396/12/01**
Update count: **0**

Registration date

2018-02-20, 1396/12/01

Registrant information

Name
Mohamad Reza Ardakani Movaghati
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

personal- medical university of Mashhad

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

2016-02-20, 1394/12/01

Actual recruitment end date

2016-10-16, 1395/07/25

Trial completion date
empty

Scientific title
Study the effect of the product contains Black Seed on the bigger stones or equal to five millimetres in patients with kidney stones without metabolic or infectious risk factors.

Public title
Efficacy of black seed (Nigella sativa) on kidney stone dissolving

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Men and women aged 20 to 60 years, people 20-60 years old with kidney stone disease that has been confirmed by ultrasound sonography Patients with kidney stones equal or larger than 5 mm diameter People who do not have poor renal and hepatic function (according to tests and records) people who are satisfied with traditional treatment

Exclusion criteria:
pregnancy breast feeding any renal disorder which requires new treatment protocols known allergy to black seed

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
Actual sample size reached: **53**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
1- Use coded questionnaires 2- The use of similar drug packs in both intervention and control groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Building Ghoreshi., Daneshgah street

City
Mashhad

Province
Razavi Khorasan

Postal code
9177501365

Approval date
2016-02-13, 1394/11/24

Ethics committee reference number
IR.MUMS.REC.1394.659

Health conditions studied

1

Description of health condition studied
kidney stone

ICD-10 code
N20.0

ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
Stone number

Timepoint
Before the intervention and 70 days after the start of taking the black seed

Method of measurement
Change in the number of stones after intervention by kidney ultrasound based on millimetres.

2

Description
Stone size

Timepoint
Before the intervention and 70 days after the start of taking the black currant.

Method of measurement
Change in the size of the stones after the intervention by kidney ultrasound based on millimetres.

Secondary outcomes

1

Description
The amount of calcium in the blood

Timepoint
Before the intervention and 70 days after the start of

taking the black seed.

Method of measurement

Photometric

2

Description

Ph level of urine

Timepoint

Before the intervention and 70 days after the start of taking the black seed

Method of measurement

pH meter

Intervention groups

1

Description

Intervention group: Capsules of black seed (500 mg twice a day) were given to patients for 10 weeks. Capsules were taken with honey syrup.

Category

Placebo

2

Description

Control group: Placebo capsules (500 mg twice a day) were given to patients for 10 weeks. Capsules were taken with honey syrup.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Mahdi yousofi

Street address

Central Clinic, Imam Reza Hospital, Bahar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad 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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohamad Reza Ardakani Movaghati

Position

Traditional Medicine Trainee

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available