Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of Alcoholic Extract of black Cumin and placebo on Stones Size of the Patients with Calcium Kidney Stones

Protocol summary

Study aim
Effect of Alcoholic Extract of black Cumin on Stones Size in Patients with Calcium Kidney Stones

Design
The clinical trial with a control group, with parallel groups, single blind, randomized, phase 2, on 60 patients.The Rand software of the excel was used for randomization.

Settings and conduct
Place of study: Urology clinic, Velayat hospital, Qazvin. Type of blinding: single blind study in which the samples (patients and control groups) don't know the type of intervention or treatment but the researcher or treatment staff are aware. It should be noted that in this study, the drug (Alcoholic extract of black cumin) and placebo (wheat flour) are given to the intervention and control group in capsules with the same shape and color.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willing to collaboration; Having calcium oxalate kidney stones; Ages between 30-60 years old; Normal physical activity level. Non-inclusion criteria: Invariability of treatment method and medications in last two months; No pregnancy and lactation; No liver disorders and diabetes

Intervention groups
Intervention group: oral administration of alcoholic extract of black Cumin capsules (two times a day, each time: 100 mg) for 12 weeks. Control group: oral administration of wheat flour capsules (two times a day). It should be noted that the supplement and placebo in the mentioned amount will be added to the patients' medication, and the patients in the experimental and control groups will receive the medications prescribed by the doctor as before the intervention.

Main outcome variables
The size of the stone; Urine oxalate; serum level of creatinine; serum level of uric acid

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200918048747N3**
Registration date: **2021-01-30, 1399/11/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-30, 1399/11/11**
Update count: **0**

Registration date
2021-01-30, 1399/11/11

Registrant information

Name
Alireza Farasat

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-04-21, 1400/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effect of Alcoholic Extract of black Cumin and placebo on Stones Size of the Patients with Calcium Kidney Stones

Public title
Effect of alcoholic extract of black Cumin on kidney stones size
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willing to collaboration Having Calcium oxalate kidney stone Invariability of treatment method and medications in last two months Normal physical activity level
Exclusion criteria:
Pregnancy and lactation Patients with liver disorders, diabetes, acute metabolic disorders and allergy Food supplement consumption from last two months to the end of the study
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation can be made in blocks which was used in this study. The participants are divided in to two groups of control and test using block randomization method. The size of each block will be equal to 2, 4 and 8 samples. After block allocation, the individuals will choose one of the treatments randomly.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this method (single blind), the samples (patients and control groups) don't know the type of intervention or treatment but the researcher or treatment staff are aware. It should be noted that in this study, the drug (Alcoholic extract of black cumin) and placebo (wheat flour) are given to the intervention and control group in capsules with the same shape and color.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences, Shahid Bahonar St.
City
Qazvin
Province
Qazvin
Postal code
15315-34199
Approval date
2019-11-20, 1398/08/29
Ethics committee reference number
IR.QUMS.REC.1398.193

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
Size of stone
Timepoint
Before and after intervention
Method of measurement
Sonography

2

Description
Urine Oxalate level
Timepoint
Before and after intervention
Method of measurement
Oxalate detection kit on urine sample

3

Description
Serum creatinine level
Timepoint
Before and after intervention
Method of measurement
Creatinine detection kit on blood sample

4

Description
Serum Uric acid level

Timepoint
Before and after intervention
Method of measurement
Uric acid detection kit on blood sample

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: oral administration of alcoholic extract of black Cumin capsules (two times a day, each time: 100 mg) for 12 weeks
Category
Treatment - Other

2

Description
Control group: oral administration of wheat flour capsules (two times a day) which is completely similar to extract capsule.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
Maryam Javadi
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Qazvin 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
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Position
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inquiries

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Person responsible for updating data

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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