

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

Email address

a.farasat@modares.ac.ir

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

Street address

Qazvin University of Medical Sciences, Shahid Bahonar street.

City

Qazvin

Province

Qazvin

Postal code

15315-34199

Phone

+98 28 3333 6001

Email

info@qums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Emam Jome

Street address

Qazvin University of Medical Sciences, Shahid Bahonar St.

City

Qazvin

Province

Qazvin

Postal code

15315-34199

Phone

+98 28 3333 6001

Email

info@qums.ac.ir

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

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Maryam Javadi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Qazvin University of Medical Sciences, Shahid Bahonar St.

City

Qazvin

Province

Qazvin

Postal code

15315-34199

Phone

+98 28 3333 6001

Email

mz_javadi46@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zohreh Aghamiri

Position

Master of Science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Qazvin University of Medical Sciences, Shahid
Bahonar St.

City

Qazvin

Province

Qazvin

Postal code

15315-34199

Phone

+98 28 3333 6001

Email

Aghamiri.zohreh.nut92@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Zohreh Aghamiri

Position

Master of Science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Qazvin University of Medical Sciences, Shahid
Bahonar St.

City

Qazvin

Province

Qazvin

Postal code

15315-34199

Phone

+98 28 3333 6001

Email

Aghamiri.zohreh.nut92@gmail.com

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