Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the effect of green tea extract on the size of urinary stone in patients with calcium kidney stones

Protocol summary

Study aim
Evaluating the effect of green tea extract on stone formation in patients with calcium oxalate kidney stones
Design
On day zero, sixth and twelfth weeks of the study, in the same laboratory, 10 cc of venous blood sample is taken. After serum separation, the urea and creatinine level in plasma of the participants will be evaluated using specific kits and ELISA method. The Sonography method will be applied for evaluating the size of stones on day of zero, the sixth and twenty first weeks of the study.
Settings and conduct
60 patients with kidney stones from (Velayat hospital, Qazvin University of Medical Sciences, Urology center) will be chosen as the patients group.
Participants/Inclusion and exclusion criteria
Willing to collaboration Having calcium oxalate kidney stones Ages between 30-60 Invariability of treatment method and medications in last two months Normal physical activity level No pregnancy and lactation No liver disorders and diabetes
Intervention groups
The participants are divided in to two groups: first intervention group (patients); oral administration of green tea extract capsules (two times a day, each time: 225 mg) for 12 weeks. second intervention group (control group); oral administration of distilled water capsules (two times a day).
Main outcome variables
The size of the stone, analyzing the biochemical factors of blood and urine

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200918048747N1**
Registration date: **2020-12-07, 1399/09/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-07, 1399/09/17**
Update count: **0**
Registration date
2020-12-07, 1399/09/17

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
2020-09-26, 1399/07/05
Expected recruitment end date
2020-12-25, 1399/10/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of green tea extract on the size of urinary stone in patients with calcium kidney stones

Public title
Evaluating the effect of green tea extract on the size of urinary stone in patients with calcium kidney stones
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
- Investigator

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. It should be noted that for the patient, specialist and the researcher, the difference of two treatments will be unclear. The control group will receive only their usual treatment.

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.

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

2019-09-01, 1398/06/10

Ethics committee reference number

IR.QUMS.REC.1398.136

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

The Oxalate, Creatinine and Uric acid level

Timepoint

Before and after intervention

Method of measurement

The detection kit

Secondary outcomes

1

Description

Size of stone

Timepoint

Before and after intervention

Method of measurement

Sonography

Intervention groups

1

Description

The participants are divided in to two groups: first intervention group (patients); oral administration of green tea extract capsules (two times a day, each time: 225 mg) for 12 weeks

Category

Treatment - Other

2

Description

Control group: second intervention group (control group);

oral administration of distilled water capsules (two times a day).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Alireza Farasat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Emam Jome

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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

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

Alireza Farasat

Position

Professor Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Person responsible for scientific inquiries

Contact

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Master of Science

Latest degree

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Other areas of specialty/work

Nutrition

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Latest degree
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Other areas of specialty/work
Nutrition

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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