

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

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

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

Evaluating the effect of green tea extract on stone formation in patients with calcium oxalate kidney stones

Last update: **2020-12-07, 1399/09/17**

Update count: **0**

#### 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.

#### Registration date

2020-12-07, 1399/09/17

#### 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

#### 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.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### 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

#### 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

#### 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).

#### Scientific title

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

#### Main outcome variables

The size of the stone, analyzing the biochemical factors of blood and urine

#### Public title

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

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200918048747N1**

Registration date: **2020-12-07, 1399/09/17**

##### 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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Qazvin University of Medical Sciences, Shahid Bahonar st.

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**Email**

info@qums.ac.ir

**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**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Shabnam Zarei

**Position**

Master of Science

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

Shabnamdiet6@gmail.com

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Shabnam Zarei

**Position**

Master of science

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

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**Email**

## 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