

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Comparison of the effect of the calcium citrate supplement with normal calcium diet on metabolic risk factors in recurrent calcium stone formers with hyperoxaluria: a randomized clinical trial

#### Protocol summary

##### Study aim

Comparison of the effect of the calcium citrate supplement with normal calcium diet on metabolic risk factors in recurrent calcium stone formers with hyperoxaluria

##### Design

randomized controlled clinical trial

##### Settings and conduct

patient recruitment will be performed in Shahid Labbafinejad stone prevention clinic. After collection of the informed consent, patients will be recruited in the study and all study variables (demographic, anthropometric, food recall questionnaire, blood, urine, and 24-hour urine sample analyses) will be collected. the patients will be randomized to intervention and control groups. The length of the study was 8 weeks. Both groups had the usual nutritional care of the stone prevention clinic, including increased fluid intake, restricted oxalate intake, increase fruit and vegetable intake, and low salt and fat intake.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Recurrent calcium stone formation; age 18-65 years; hyperoxaluria; dietary calcium intake less than 800 mg per day Exclusion criteria: primary or enteric hyperoxaluria; using any drug that could affect oxalate or calcium metabolism; History of diabetes mellitus, hepatic failure, thyroid or parathyroid diseases, cancers or immunologic diseases, chronic kidney disease, Urinary tract infection, chronic diarrhea; Pregnancy or lactation

##### Intervention groups

Intervention group: 800 mg/day calcium intake plus a diet containing 200 mg of calcium Control group: dietary intake of 1000 milligram calcium

##### Main outcome variables

24-hour urine oxalate 24-hour urine calcium 24-hour urine magnesium 24-hour urine creatinine 24-hour urine

sodium 24-hour urine potassium 24-hour urine citrate 24-hour urine calcium-oxalate supersaturation 24-hour urine calcium-phosphate supersaturation 24-hour urine uric acid supersaturation Calcium citrate supplement compliance morning urine pH

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160206026406N3**

Registration date: **2019-08-13, 1398/05/22**

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

Last update: **2019-08-13, 1398/05/22**

Update count: **0**

##### Registration date

2019-08-13, 1398/05/22

##### Registrant information

##### Name

Sanaz Tavasoli

##### Name of organization / entity

Urology and Nephrology Research Center, Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2256 7222

##### Email address

s.tavasoli@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

**Expected recruitment end date**

2021-03-21, 1400/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of the calcium citrate supplement with normal calcium diet on metabolic risk factors in recurrent calcium stone formers with hyperoxaluria: a randomized clinical trial

**Public title**

Comparison of the effect of the calcium citrate supplement with normal calcium diet on metabolic risk factors in recurrent calcium stone formers with hyperoxaluria

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Recurrent stone former Hyperoxaluria (24hr Urine Oxalate between 40-80 mg) Baseline dietary calcium intake less than 800 mg/day The desire to collaborate in the study

**Exclusion criteria:**

Enteric or primary hyperoxaluria (24 hours urine oxalate more than 80 mg) Taking Thiazides or any medicine that has an effect on calcium metabolism Taking any medicine that has an effect on oxalate metabolism Taking vitamin B6 Hepatitis, diabetes, thyroid diseases, hyperparathyroidism, immunological diseases, cancers, chronic diarrhea, chronic kidney diseases and urinary tract infection Pregnancy and lactation

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **66**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization with the block size of four will be used, to randomly allocate the patients to loading and maintenance treatment groups and balance patient allocation between groups. Random Allocation software will be used to generate random sequences. Given the random sequences generated, patients will be divided into two groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Urology and Nephrology research center

**Street address**

Urology and Nephrology Research Center, No. 103, Shahid Jafari (9th Boostan) St., Pasdaran Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1666663111

**Approval date**

2015-03-14, 1393/12/23

**Ethics committee reference number**

unrc.93123-19

**Health conditions studied****1****Description of health condition studied**

Recurrent calcium stone formers with hyperoxaluria

**ICD-10 code**

N20.0

**ICD-10 code description**

Calculus of kidney

**Primary outcomes****1****Description**

24hr Urine Oxalate

**Timepoint**

Before the intervention, 8 weeks after intervention

**Method of measurement**

Enzymatic method

**2****Description**

Calcium oxalate supersaturation

**Timepoint**

Before the intervention, 8 weeks after intervention

**Method of measurement**

Calculation by LITHORISK software

## Secondary outcomes

### 1

**Description**

Urine pH

**Timepoint**

Before the intervention, 8 weeks after intervention

**Method of measurement**

pH meter

### 2

**Description**

24 hour urine oxalate

**Timepoint**

Before the intervention, 8 weeks after intervention

**Method of measurement**

Enzymatic method

## Intervention groups

### 1

**Description**

Intervention group one: Patients receiving daily 800 mg calcium (in two divided doses with lunch and dinner in the form of calcium citrate) plus a diet containing 200 mg of calcium in breakfast meal

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group two: Patients consume adequate dietary calcium (1000 mg of calcium, divided in meals, 200 mg of breakfast, 400 mg with lunch and 400 mg with dinner)

**Category**

Lifestyle

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Stone prevention clinic- Labafinejad hospital - Urology and Nephrology Research Center

**Full name of responsible person**

Sanaz Tavasoli

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No 103, 9th Boustan St., Pasdaran Ave.

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Shabnam Golshan

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shgolshan2@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Urology and Nephrology Research Center

**Full name of responsible person**

Sanaz Tavasoli

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

The information about the type of treatment and the results of 24-hour urine analyses will be available.

### When the data will become available and for how long

The data could be available one year after the publication of the results.

### To whom data/document is available

Data will be available for academic faculty members and researchers.

### Under which criteria data/document could be used

The control of the data and supplementary analyses of the data could be performed under copyright law.

### From where data/document is obtainable

Urology and Nephrology Research Center: Dr. Sanaz Tavasoli: s.tavasoli@sbmu.ac.ir Ms. Shabnam Golshan: +98-21-22567222

### What processes are involved for a request to access data/document

The applicant must submit a written request to the Urology and Nephrology Research Center. After the approval of the center and the PI of the proposal, the data will be available to the applicant.

### Comments