Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 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
Street address
No 103, 9th Boustan St., Pasdaran Ave.
City
Tehran
Province
Tehran
Postal code
1666661111
Phone
+98 21 2256 7222
Fax
+98 21 2256 7282
Email
sanaz.tavasoli@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shabnam Golshan
Street address
No 103, 9th Boustan St., Pasdaran Ave.
City
Tehran
Province
Tehran
Postal code
1666661111
Phone
+98 21 2256 7222
Fax
+98 21 2256 7282
Email
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
Street address
No 103, 9th Boustan St., Pasdaran Ave.

City
Tehran
Province
Tehran
Postal code
1666661111
Phone
+98 21 2256 7222
Email
sanaz.tavasoli@gmail.com

Person responsible for scientific 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
Street address
No 103, 9th Boustan. St., Pasdaran Ave.
City
Tehran
Province
Tehran
Postal code
1666661111
Phone
+98 0212256722
Email
sanaz.tavasoli@gmail.com

Person responsible for updating data

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
Street address
No 103, 9th Boustan. St., Pasdaran Ave.
City
Tehran
Province
Tehran
Postal code
1666661111
Phone
+98 212256722
Email
sanaz.tavasoli@gmail.com

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