Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of oral magnesium citrate and magnesium oxide supplementation on hyperoxaluria and calcium oxalate supersaturation in kidney stone patients

Protocol summary

Study aim
The effect of oral magnesium citrate and magnesium oxide supplementation on hyperoxaluria and calcium oxalate supersaturation in kidney stone patients

Design
Clinical trial with control group,parallel groups, single blinded, randomised

Settings and conduct
Patient recruitment will be performed in Shahid Labbafinejad stone prevention clinic. After collection of the informed consent, all study variables (demographic, anthropometric, food recall questionnaire, blood, urine, and 24-hour urine sample analyses) will be collected from participants. the patients will be randomized to intervention and control group. All groups had the usual nutritional care of the stone prevention clinic. After 8 weeks duration of study, variables will be assessed again.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with a history of kidney stone; Hyperoxaluria (24-hour urine oxalate over 40 and less than 80 mg); willingness to cooperate in the study. Exclusion criteria: Primary or enteric hyperoxaluria (urine oxalate>80 mg/24h); Taking any drugs which affects calcium metabolism, including thiazides; Taking any drugs which affects oxalate metabolism or calcium oxalate supersaturation, including vitamin B6; History of diabetes mellitus, hepatic failure, thyroid or parathyroid diseases, chronic kiodney disease (CKD), Urinary tract infection (UTI), chronic diarrhea or immunologic diseases; Pregnancy or lactation

Intervention groups
Intervention group: Magnesium citrate (360 mg, three 120 mg doses with breakfast, lunch and dinner) 33 patients for 8 weeks Intervention group: Magnesium oxide (360 mg, three 120 mg doses with breakfast, lunch and dinner) 33 patients for 8 weeks Control group: placebo with dietary recommendation

Main outcome variables
24 hour urine oxalate Calcium oxalate supersaturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191026045244N1**
Registration date: **2019-12-03, 1398/09/12**
Registration timing: **retrospective**

Last update: **2019-12-03, 1398/09/12**
Update count: **0**

Registration date
2019-12-03, 1398/09/12

Registrant information

Name
Maryam Taheri

Name of organization / entity
Urology and Nephrology Research Center,Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

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taheri233@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-06-21, 1395/04/01

Expected recruitment end date
2018-06-22, 1397/04/01

Actual recruitment start date
2016-06-21, 1395/04/01
Actual recruitment end date
2019-01-10, 1397/10/20
Trial completion date
2019-04-21, 1398/02/01

Scientific title
The effect of oral magnesium citrate and magnesium oxide supplementation on hyperoxaluria and calcium oxalate supersaturation in kidney stone patients

Public title
The effect of magnesium supplementation on hyperoxaluria and calcium oxalate supersaturation in kidney stone patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Hyperoxaluria (24-hour urine oxalate over 40 and less than 80 mg) Patients with a history of kidney stone referred to kidney stone prevention clinic of Labbafinejad at least 20 days since the last treatment they have at least 3 months since following general dietary advice on recurrence prevention (drinking advice, high oxalate food restriction, animal protein restriction, fruit and vegetable intake encouragement, salt restriction and fat intake modification) willingness to cooperate in the study
Exclusion criteria:
Primary or enteric hyperoxaluria (urine oxalate>80 mg/24h) Taking any drugs which affects calcium metabolism, including thiazides, potassium citrate, calcium supplement, magnesium supplement and Laxatives Taking any drugs which affects oxalate metabolism or calcium oxalate supersaturation, including vitamin B6 History of diabetes mellitus, hepatic failure, thyroid or parathyroid diseases, chronic kiodney disease (CKD), Urinary tract infection (UTI), chronic diarrhea or immunologic diseases Pregnancy or lactation
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **99**
Actual sample size reached: **99**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization with the block size of four was used, to randomly allocate the patients to Magnesium oxide, Magnesium citrate and Placebo groups and balance patient allocation between groups. Random Allocation software was used to generate random sequences. Given the random sequences generated, patients were divided into three groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The form of the drug in the three groups of magnesium oxide, magnesium citrate and placebo was quite similar and participants would not be informed about participation in which of the three study groups.
Placebo
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
1666668111
Approval date
2015-03-14, 1393/12/23
Ethics committee reference number
931223.11

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
24 hour 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
24 hour urine magnesium
Timepoint
Before the intervention, 8 weeks after intervention
Method of measurement
Chemical Method - Calorimetry

Intervention groups

1

Description
Intervention group: Magnesium Oxide
Category
Treatment - Drugs

2

Description
Intervention group: Magnesium Citrate
Category
Treatment - Drugs

3

Description
Control group: Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Stone prevention clinic- Labafinejad hospital - Urology and Nephrology Research Center
Full name of responsible person
Maryam Taheri
Street address
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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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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maryam Taheri
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Urology
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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. Maryam Taheri: taheri233@yahoo.com/ 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