Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparative study of the effects of hypovitaminosis D treatment with loading and maintenance methods on serum vitamin D status, 24-hour urine calcium, and serum and urine oxidative stress status in patients with calcium kidney stones

Protocol summary

Study aim
Determine the effects of hypovitaminosis D treatment with loading and maintenance methods on serum vitamin D status, 24-hour urine calcium, and serum and urine oxidative stress status in patients with calcium kidney stones

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 will be collected. The patients will be randomized to study groups. Both groups will have the usual nutritional care of the stone prevention clinic. All study variables will be assessed 12 weeks later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 70; serum level of vitamin D 10-20 ng/ml; BMI of less than 30; willingness to collaborate in the study. Exclusion criteria: Known cystine or struvite kidney stones; hypercalcemia; 24-hour urine calcium higher than 300 mg/24h; stone pass or gross hematuria in the last 2 months; new prescription or change in the dose of thiazide drugs or any medicine that affect calcium metabolism; Taking antiepileptic or glucocorticoid drugs or any medication that affect vitamin D absorption; history of hepatic diseases, sarcoidosis, diabetes, thyroid, hyperparathyroidism, immunological diseases, cancers, chronic renal failure, urinary tract infections, fat malabsorption, celiac disease, cystic fibrosis; pregnancy and lactation

Intervention groups
Intervention group 1: vitamin D with a dose of 50000 IU weekly for 8 weeks. Intervention group 2: vitamin D with a dose of 2000 IU daily for 12 weeks.

Main outcome variables
24-hour urine calcium; serum vitamin D; serum and urine MDA; serum and urine total antioxidant capacity.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160206026406N4**
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)

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+98 21 2256 7222

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-28, 1397/05/06

Expected recruitment end date
2020-02-25, 1398/12/06
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effects of hypovitaminosis D treatment with loading and maintenance methods on serum vitamin D status, 24-hour urine calcium, and serum and urine oxidative stress status in patients with calcium kidney stones

Public title
Evaluation of vitamin D deficiency treatment in patients with calcium kidney stones
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Serum vitamin D 10-20 ng/ml body mass index under 30 Willingness to cooperate in the study
Exclusion criteria:
Known Cystine or Struvite kidney stones Hypercalcemia 24-Hour urine calcium higher than 300 mg / 24h Stone pass or gross hematuria in the last 2 months New prescription or changing the dose of thiazide drugs or any drug that has an effect on calcium metabolism Taking antiepileptic or glucocorticoid drugs or any medication that has an effect on vitamin D absorption. Any history of the following diseases: hepatic diseases, diabetes mellitus, thyroid diseases, hyperparathyroidism, immunological diseases, cancers, chronic diarrhea, chronic kidney diseases, urinary tract infection, fat malabsorption, celiac disease, cystic fibrosis. Pregnancy and lactation
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
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 Tehran University of Medical Sciences
Street address
Headquarters of the Ministry of Health- Simaye iran Avenue-shahrak qods (west) tehran
City
tehran
Province
Tehran
Postal code
1467664961
Approval date
2018-06-20, 1397/03/30
Ethics committee reference number
IR.TUMS.VCR.REC.1397.193

Health conditions studied

1

Description of health condition studied
Recurrent calcium stone formers
ICD-10 code
N20.0
ICD-10 code description
Calculus of kidney

2

Description of health condition studied
Vitamin D deficiency
ICD-10 code
E55
ICD-10 code description
Vitamin D deficiency

Primary outcomes

1

Description
24-hour urine calcium level
Timepoint
Before the intervention and 3 months later
Method of measurement
Colorimetry

2

Description
Serum vitamin D
Timepoint
Before the intervention and 3 months later
Method of measurement
ELISA

3

Description
Serum and urine Malondialdehyde
Timepoint
Before the intervention and 3 months later
Method of measurement
Colorimetry

4

Description
Serum and urine total antioxidant capacity
Timepoint
Before the intervention and 3 months later
Method of measurement
Colorimetry

Secondary outcomes

1

Description
Serum PTH level
Timepoint
Before the intervention and 3 months later
Method of measurement
ELISA

2

Description
Serum calcium
Timepoint
Before the intervention and 3 months later
Method of measurement
Colorimetry

3

Description
24 hour urine creatinine
Timepoint
Before the intervention and 3 months later
Method of measurement
Colorimetry

4

Description
24 hour urine urea
Timepoint
Before the intervention and 3 months later
Method of measurement
Colorimetry

5

Description
24 hour urine sodium
Timepoint
Before the intervention and 3 months later
Method of measurement
Ion-selective electrode potentiometry (ISE)

6

Description
Calcium oxalate supersaturation
Timepoint
Before the intervention and 3 months later
Method of measurement
Calculated by LITHORISK software

7

Description
Calcium phosphate supersaturation
Timepoint
Before the intervention and 3 months later
Method of measurement
Calculated by LITHORISK software

Intervention groups

1

Description
Intervention group 1: This group receives vitamin D with a dose of 50000 IU weekly for 8 weeks.
Category
Treatment - Drugs

2

Description
Intervention group 2: The group receives vitamin D with a dose of 2000 IU daily for 12 weeks.
Category
Treatment - Drugs

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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urology and nephrology research center
Full name of responsible person
Shabnam Golshan
Street address
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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
Urology and nephrology research center
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
Tehran University of Medical Sciences
Full name of responsible person
Lilit Sardari Masihi
Position
Master of Science Student in nutrition
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Name of organization / entity
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Sanaz Tavasoli
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Person responsible for updating data

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Nutrition
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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 original outcome can be shared.

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