

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)

Phone

+98 21 2256 7222

Email address

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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

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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
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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

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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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