

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

evaluation of effect of Vitamin D supplementation on hypercalciuria in vitamin D deficient recurrent stone former patients

Protocol summary

Study aim

evaluation of effect of vitamin D supplement on urinary calcium and stone forming rate of patients with urilithiasis and vitamin D deficiency

Design

patients aged 20 to 65 years who suffered vitamin D deficiency (serum vitamin D level < 30 ng/ml) and also history of nephrolithiasis with at least two episodes of stone recurrence or increase in stone size within the last five years who have not exclusion criteria will be included. serum levels of calcium, creatinine, uric acid, 25OHD, and parathormone and 24-hour urine concentration of creatinine, citrate, oxalate, sodium, uric acid, and calcium at the time of enrollment and three months after starting the vitamin D consumption will be measured. then this parameters with information like age,sex,BMI and hypertension if exists will be analyzed with SPSS software.

Settings and conduct

out patients who referred to nephrology department of Shariati hospital or private clinic of the researcher

Participants/Inclusion and exclusion criteria

urinary stone former patients who have vitamin D deficiency and sign the constant form and have not below criteria: pregnant patients, hypercalcemia (baseline calcium level of ≥ 10.4 mg/dl), medications that affect calcium and bone metabolism (such as calcium) or calcium excretion (such as steroidal or hormonal drugs), previous history of primary hyperparathyroidism or other systemic diseases (cancer, alcoholic liver disease and osteoporosis) patients who had invasive diagnostic or therapeutic interventions on renal stones within the last month prior to enrollment known case of uric acid ,cysteine or steruvite urinary stone

Intervention groups

All 30 patients with inclusion criteria who have not exclusion criteria receive vitamin D pearl and after and before intervention lab test will be compare

Main outcome variables

changes rate of 24 hour urine calcium and amount of new stone formation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180108038262N2**

Registration date: **2018-08-10, 1397/05/19**

Registration timing: **retrospective**

Last update: **2018-08-10, 1397/05/19**

Update count: **0**

Registration date

2018-08-10, 1397/05/19

Registrant information

Name

Zahra Shafii

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2315 2013

Email address

shafii_zahra@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-01-01, 1392/10/11

Expected recruitment end date

2015-12-29, 1394/10/08

Actual recruitment start date

2014-01-01, 1392/10/11

Actual recruitment end date

2015-12-20, 1394/09/29

Trial completion date

empty

Scientific title

evaluation of effect of Vitamin D supplementation on hypercalciuria in vitamin D deficient recurrent stone former patients

Public title

The use of vitamin D supplementation and risk of hypercalciuria

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

urinary stone former vitamin D deficiency sign the constant form

Exclusion criteria:

pregnant patients hypercalcemia (baseline calcium level of ≥ 10.4 mg/dl) medications that affect calcium and bone metabolism (such as calcium) or calcium excretion (such as steroidal or hormonal drugs), previous history of primary hyperparathyroidism or other systemic diseases (cancer, alcoholic liver disease and osteoporosis) patients who had invasive diagnostic or therapeutic interventions on renal stones within the last month prior to enrollment known case of uric acid ,cysteine or steruvite urinary stone

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Tehran University Of Medical Science Ethics

Committee

Street address

Ghods Street,Keshavarz Blvd, Central Organization of University of Medical Science, 6th floor

City

Tehran

Province

Tehran

Postal code

1416753955

Approval date

2013-12-22, 1392/10/01

Ethics committee reference number

91-02-146-18306

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

urolithiasis

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

2**Description of health condition studied**

vitamin D deficiency

ICD-10 code

E55.9

ICD-10 code description

Vitamin D deficiency, unspecified

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

amount of increase in urinary calcium

Timepoint

before and after 3 month of vitamin D prescription

Method of measurement

measurement of calcium in 24 hour urine

2**Description**

urinary stone formation

Timepoint

3 month after treatment

Method of measurement

ultrasound examination

Secondary outcomes**1****Description**

serum parathyroid change

Timepoint

before and 3 month after vitamin D prescription

Method of measurement

laboratory measurement

Intervention groups

1

Description

Intervention group: administration of vitamin D pearl 50000 unit weekly for 2 month and then every 2 weak until third month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hoapital

Full name of responsible person

Mohammadreza Ganji

Street address

Shariati Hospital, Jalal Ale Ahmad Ave, North Karegar St, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeeyan

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Ganji

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available