

# 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  $\geq 10.4$  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  $\geq 10.4$  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

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713135

**Phone**

+98 21 8490 1000

**Email**

mrezaganji@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Sahraeeyan

**Street address**

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

**City**

tehran

**Province**

Tehran

**Postal code**

1417653761

**Phone**

+98 21 8163 3619

**Email**

rmo@tums.ac.ir

**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

**Street address**

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

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**Email**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

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Mohammad Reza Ganji

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Professor

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**Email**  
mrezaganji@yahoo.com

## Person responsible for updating data

### 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  
**Street address**  
Shariati Hospital, Jalal Ale Ahmad Ave, North Karegar  
St, Tehran, Iran  
**City**  
Tehran  
**Province**

Tehran  
**Postal code**  
1411713135  
**Phone**  
+98 21 8490 1000  
**Email**  
mrezaganji@yahoo.com

## 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