

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Feb 2026

### Evaluation of the effect of vitamin D supplementation in post menopausal patients with urgent urinary incontinency and vitamin D deficiency

#### Protocol summary

##### Study aim

Evaluation of the effect of oral vitamin D supplementation in improving the symptoms of urgent urinary incontinence in postmenopausal women with vitamin D deficiency

##### Design

In this double-blind randomized clinical trial, postmenopausal women between 50 and 80 years of age with symptoms of urgent urinary incontinency and serum vitamin D3 level of less than 30 ng / ml will be randomly assigned into two groups. Patients in intervention group will receive 50,000 U vitamin D3 weekly for 8 weeks. the control group will receive placebo for the same period. then the patients will be assessed for clinical symptoms and serum level of vitamin D.

##### Settings and conduct

Ninety postmenopausal women between 50 and 80 years of age who were referred to the GYN clinic of Mahdiah Hospital with symptoms of urgent incontinence or history of nocturia. These patients will be randomly assigned into two groups; one group will receive vitamin D3 weekly for 8 weeks and the other group receives placebo weekly for the same period. In the follow-up, patients will be assessed for any improvement in symptoms and possible side effects of the drug. The Modified LUTS EPINCONT questionnaire will be used to assess the symptoms and severity of urinary incontinence. Likert Scale will also be used for assessment of patient's satisfaction after treatment.

##### Participants/Inclusion and exclusion criteria

Postmenopausal women between 50 and 80 years of age , serum level of vitamin D3 less than 30 ng / ml who have symptoms of urgent urinary incontinence with any severity

##### Intervention groups

Intervention group will receive 50,000 units of vitamin D for 8 weeks and the control group will receive placebo for the same period.

##### Main outcome variables

Oral vitamin D supplementation is effective in improving nocturia and reducing urgent urinary incontinence symptoms in postmenopausal women with vitamin D deficiency.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200417047109N1**

Registration date: **2020-11-24, 1399/09/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-11-24, 1399/09/04**

Update count: **0**

##### Registration date

2020-11-24, 1399/09/04

##### Registrant information

##### Name

mahsa arjmand

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5541 1259

##### Email address

drmahsaarjmand@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2021-08-23, 1400/06/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of vitamin D supplementation in post menopausal patients with urgent urinary incontinency and vitamin D deficiency

**Public title**

Effect of vitamin D supplementation in urinary incontinency

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Menopausal women between 50 and 80 years of age  
Serum level of vitamin D3 below 30ng / ml  
Urgent urinary incontinence of any degree  
Written informed consent for participation in the study

**Exclusion criteria:**

Any underlying condition that impairs vitamin D absorption, such as IBD and gastric bypass surgery  
Chronic liver or kidney disease  
Any neurological disorder that affects the urinary system such as MS, degenerative muscle disorders, CVA, and Spinal cord injury  
Diabetes  
History of chronic cough or chronic constipation  
History of vesiculovaginal fistula  
Progesterone and estrogen supplement in the last six months  
Urinary tract infection during the test  
Severe bladder prolapse (stages 3 and 4 cystocele and apical).  
Patients using diuretics  
Not knowing Persian language

**Age**

From **50 years** old to **80 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization block method is used for randomization. The letters A and B are written on paper and placed in an envelope. By selecting one of the papers in the envelope, the patient determines to be in the group receiving medication or placebo.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this double-blind study, the patient and the researcher do not know which group receives the drug or placebo. The drug and placebo will be given to the patient in separate envelopes by the health care provider. The researcher will gather information blindly at the end of the study through an interview with the patient.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

**Street address**

No 10, Rezaee Alley, Ostadzade Alley, Anari taft St, Kamali St

**City**

Tehran

**Province**

Tehran

**Postal code**

1317883611

**Approval date**

2020-08-12, 1399/05/22

**Ethics committee reference number**

435.IR.SBMU.RETECH.REC.1399

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

urgent urinary incontinency

**ICD-10 code**

R39.15

**ICD-10 code description**

Urgency of urination

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

Serum vitamin D level

**Timepoint**

Vitamin D level before and after 8 weeks of vitamin D administration

**Method of measurement**

Serum Level

**2****Description**

Severity of urinary incontinence symptoms before and after treatment

**Timepoint**

Before and after treatment

### Method of measurement

Modified LUTS EPINCONT questionnaire (based on total incontinence frequency and leakage volume)

### 3

#### Description

The degree of disturbance in the patient's quality of life due to urinary incontinency (before and after treatment)

#### Timepoint

At the beginning of the study and after the end of treatment

#### Method of measurement

Modified LUTS EPINCONT questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Oral pearl Vitamin D 50,000 units weekly for up to 8 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Oral placebo once a week for up to 8 weeks

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mahdiyeh Hospital

##### Full name of responsible person

Mahsa Arjmand

##### Street address

Shahid Rajabnia St., Shishegar Khaneh Alley Fadaian Islam St., Shoush Square

##### City

Tehran

##### Province

Tehran

##### Postal code

1185817311

##### Phone

+98 21 5506 2628

##### Email

mahdiyeh\_hospital@sbm.ac.ir

##### Web page address

<http://www.mmc.sbm.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Fares Najari

##### Street address

Shousha Square, Fadaian-e-Islam Street, Shishegar Khane Alley, Shahid Rajab Nia Street

##### City

Tehran

##### Province

Tehran

##### Postal code

1185817311

##### Phone

+98 21 5506 2627

##### Email

mahdiyeh\_hospital@sbm.ac.i

#### 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

Mahsa Arjmand

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Shousha Square, Fadaian-e-Islam Street, Shishegar Khane Alley, Shahid Rajab Nia Street

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mahdiyeh\_hospital@sbmu.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahsa Arjmand

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

No 10, Anari Taft, Kamali street, south kargar, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1185817311

**Phone**

+98 21 5541 1259

**Fax**

**Email**

drmahsaarjmand@sbmu.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mahsa Arjmand

**Position**

Resident

**Latest degree**

Medical doctor

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**Phone**

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**Email**

mahdiyeh\_hospital@sbmu.ac.ir

## 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