

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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@sbm.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

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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

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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

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

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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