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 Mahdieh 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

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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
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Shahid Rajabnia St., Shishegar Khaneh Alley Fadaiyan Islam St., Shoush Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fares Najari
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Shousha Square, Fadaiyan-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