Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Effect of Vitamin D3 Supplementation on the severity of Stress Urinary Incontinence (SUI) in premenopausal women; A double-blind clinical trial

Protocol summary

Study aim

Effect of vitamin D3 supplementation on the severity of Stress Urinary Incontinence (SUI) in premenopausal women

Design

Clinical trial with control group, With parallel groups, double blind, Randomized

Settings and conduct

In this clinical trial, 60 premenopausal women referred to the gynecology clinic affiliated to Kerman University of Medical Sciences will be participated in the study and will be allocated to quaternary blocks by random blocking method. They will be divided in two groups of intervention (vitamin D) and control (placebo).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, Age : 40 to 49 years, Serum level of vitamin D less than 30 ng/ml, Confirmation of the diagnosis of stress urinary incontinence by a physician; exclusion criteria: reluctance to continue collaborating in the study, Any disorder that prevents the absorption of vitamin D. Such as inflammatory bowel disease (IBD), Chronic diabetes, Chronic liver or kidney disease, Hysterectomy, History of neoplasia Urinary-genital system, Any neurological disease that affects the urinary system or bowel movements, including multiple sclerosis, Participants who have used estrogen or progesterone in the last 6 months.

Intervention groups

In the intervention group, participants will be requested use of 50,000 units of vitamin D capsules weekly for 12 weeks in addition to daily Kegel exercise. In the control group, participant will be requested use of placebo capsules weekly for 12 weeks in addition to daily Kegel exercise.

Main outcome variables

Stress urinary incontinence

General information

Reason for update

Acronym

SUI

IRCT registration information

IRCT registration number: **IRCT20190724044318N2**
Registration date: **2021-02-11, 1399/11/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-11, 1399/11/23**
Update count: **0**

Registration date

2021-02-11, 1399/11/23

Registrant information

Name

maryam alikamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3342 3494

Email address

m_kamali1984@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Vitamin D3 Supplementation on the severity of Stress Urinary Incontinence (SUI) in premenopausal women; A double-blind clinical trial

Public title
Effect of Vitamin D3 Supplementation on the severity of Stress Urinary Incontinence (SUI) in premenopausal women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age : 40 to 49 years. Serum level of vitamin D3 less than 30 ng/ml Confirmation of the diagnosis of stress urinary incontinence by a physician Having a telephone line to follow up the intervention Having at least literate

Exclusion criteria:
Use of participants from treatments other than the recommended treatment Any disorder that prevents the absorption of vitamin D3. Such as inflammatory bowel disease (IBD) . Chronic diabetes Chronic liver or kidney disease Hysterectomy History of neoplasia Urinary-genital system Any neurological disease that affects the urinary system or bowel movements, including multiple sclerosis People who have used estrogen or progesterone in the last 6 months.

Age
From **40 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, participants will be selected based on referring to the gynecology clinic affiliated to Kerman University of Medical Sciences and provided they have all the inclusion criteria. The method of assigning individuals is random and in the method of random permutation blocks with block size 4 (using the table related to random permutations) and with a ratio of 1 to 1. The randomization list is prepared by a statistician. Codes assigned to eligible individuals will be placed in sealed envelopes by someone outside the study who is unaware of the research objectives. Then, after identifying all the members of the group, the intervention will be done individually in 12 weeks.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double-blind study, researchers and patients did not know the type of intervention and drug delivery to two groups (vitamin D-placebo) by trained midwives a women's clinic affiliated with Kerman University of Medical Sciences, which does not know the nature of the research, will be held.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences

Street address
Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2021-01-04, 1399/10/15

Ethics committee reference number
IR.KMU.REC.1399.555

Health conditions studied

1

Description of health condition studied
Stress Urinary Incontinence

ICD-10 code
N39.3

ICD-10 code description
Stress incontinence (female) (male)

Primary outcomes

1

Description
Stress Urinary Incontinence

Timepoint
Before the intervention and 4th – 8th and 12th weeks of the intervention

Method of measurement
ICIQ-SF standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vitamin D capsule 5000 units prepared by Dana Pharmaceutical Company should be taken weekly for 12 weeks along with Kegel exercise. Kegel exercise is taught to people in a face-to-face session for 10 minutes at first and the pamphlet related to Sports will be provided to them.

Category

Treatment - Drugs

2

Description

Control group: Take a placebo capsule prepared by Dana Pharmaceutical Company on a weekly basis for 12 weeks with Kegel exercise. Kegel exercise is taught to people in a face-to-face session for 10 minutes at first and the pamphlet related to Sports will be provided to them.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Women Clinic affiliated to Kerman University of Medical Sciences

Full name of responsible person

Maryam Ali Kamali

Street address

Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3342 5400

Email

m_kamali1984@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

Ebn-e-Sina St.,Jahad Blvd., Kernan,Iran

City

Kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3855

Email

vcr@kmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Maryam Ali Kamali

Position

Midwife

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Maryam Ali Kamali

Position
Midwife
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Maryam Ali Kamali
Position
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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