Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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
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7616913555
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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
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Kerman
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7619813159
Phone
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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

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Full name of responsible person
Maryam Ali Kamali

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

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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