Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Investigating the effect of vitamin D supplementation on the sexual function of women in reproductive age with type 2 diabetes in the vitamin D group compared to the placebo group

Protocol summary

Study aim

Determining the effect of vitamin D on the sexual performance of women of reproductive age with type 2 diabetes referred to Isfahan Endocrine and Metabolism Research Center in 1403

Design

This study is a double-blind randomized clinical trial that is conducted on 100 women with type 2 diabetes of reproductive age who meet the inclusion criteria. The samples have insufficient levels of vitamins (10-30 ng/ml), which are randomly assigned to the intervention group (weekly prescription of Vitamin D 50000) and the control group (weekly placebo prescription) by random number table.

Settings and conduct

Women of reproductive age who are suffering from type 2 diabetes and have a document at Isfahan Endocrine Center are included in the study. and who Uses a random number table, based on the number, even numbers are placed in the intervention group and odd numbers are placed in the control group (Weekly administration for 12 weeks) and the researchers and participants are blinded. Finally, the questionnaire is completed.

Participants/Inclusion and exclusion criteria

Married women aged between 18 to 49 years; Exclusion of individuals with various diseases associated with sexual dysfunction; Exclusion of individuals taking medications known to affect sexual performance; Participants must have been diagnosed with Type 2 Diabetes for at least one year; Exclusion of individuals who have taken vitamin D supplements within the three months before the study; Participants must have normal levels of serum calcium, phosphorus, and albumin; Having insufficient vitamin D level

Intervention groups

Women of reproductive age who have type 2 diabetes and their vitamin D level is between 10_30 ng/ml. In the intervention group, Pearl has 50,000 units of vitamin D and in the control group, a placebo is administered weekly.

Main outcome variables

sexual function score; depression score; Vitamin D serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150624022896N3**
Registration date: **2024-02-25, 1402/12/06**
Registration timing: **prospective**

Last update: **2024-02-25, 1402/12/06**
Update count: **0**

Registration date

2024-02-25, 1402/12/06

Registrant information

Name

Maryam Kianpour

Name of organization / entity

School of Nursing and Midwifery, Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-08, 1403/01/20

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of vitamin D supplementation on the sexual function of women in reproductive age with type 2 diabetes in the vitamin D group compared to the placebo group

Public title

Investigating the effect of vitamin D on sexual function of women in reproductive age with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married women between 18 to 49 years old Not suffering from a wide range of diseases that lead to sexual dysfunction Including: multiple sclerosis and any central nervous system disorders, mental disorders, mental retardation, vasculitis, uncontrolled hypo and hyperthyroidism, anatomical defects of the reproductive system, tumors and tumors and cancer Not taking drugs affecting sexual function Including: H2 receptor blockers, sleeping pills, cardiac and antihypertensive drugs, anticonvulsants, narcotic drugs, anticancer drugs and corticosteroids, antihistamines, opioids and alcohol and psychotropic drugs, barbiturates Gynecologic health and absence of endometriosis Absence of erectile disorders in the husband Minimum literacy level of the participants Self-reported absence of alcohol and smoking addiction by the women Awareness of place and time Satisfaction and willingness to participate in research suffering from Type 2 diabetes for at least one year Not taking vitamin D supplements at least three months before entering the study Have normal levels of serum Calcium, Phosphorus, and Albumin Body mass index (BMI) should be less than 30 Absence of malabsorption disorders Having insufficient vitamin D level (10 – 30 ng/ml)

Exclusion criteria:

Being pregnant or in the the firs trimester after delivery Surgical history of oophorectomy, hysterectomy, and mastectomy Early menopause (age less than 40 years)

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 100 participants will randomly be divided into two groups that receive either medication (n=50) or a placebo (n=50) daily during the follow-up. Random allocation will be carried out using the permuted block randomization method with sizes of 2, 4, and 6. The random sequences will be generated by the “blockrand” package in R. The capsules (placebo/trial medication) will be allocated to participants via coded drug containers of identical appearance.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. After random grouping, the samples are divided into two control and intervention groups, the researcher and the samples do not know about this grouping, only the drug and placebo codes given to the people are recorded in their questionnaire.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Ave., Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

7346181746

Approval date

2023-12-26, 1402/10/05

Ethics committee reference number

IR.MUI.MED.REC.1402.361

Health conditions studied

1

Description of health condition studied

Sexual Dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known

physiological condition

2

Description of health condition studied
Type 2 Diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Sexual function
Timepoint
Before the intervention and 13 weeks after the intervention
Method of measurement
Female Sexual Function Index Questionnaire (FSFI)

Secondary outcomes

1

Description
Vitamin D serum level
Timepoint
Before intervention
Method of measurement
HPLC kit (high performance liquid chromatography

2

Description
Depression score
Timepoint
Before intervention
Method of measurement
DASS21 questionnaire score

Intervention groups

1

Description
Intervention group: Weekly prescription of Pearl Vitamin D with a dose of 50,000 made by Tehran Daru Company for 12 weeks after lunch to increase drug absorption.
Category
Treatment - Drugs

2

Description
Control group: Weekly administration of vitamin D placebo made by Tehran Daru Company for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Endocrine and Metabolism Research Center
Full name of responsible person
Dr Mansour Siavash Dastjerdi
Street address
Khoram Ave, Jomhouri Square, Isfahan, IRAN
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Email
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Web page address
https://mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Shakouri Jobani

Position

Midwifery MA student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Full name of responsible person

Maryam Kianpour

Position

Associate profesor

Latest degree

Ph.D.

Other areas of specialty/work

Gynecology and Obstetrics

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Nursing and Midwifery Research Center- Nursing and Midwifery faculty- Isfahan University of Medical Sciences- Hezar gerib Ave - Isfahan

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Other areas of specialty/work

Gynecology and Obstetrics

Street address

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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