

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Feb 2026

Effect of Vitamin D Supplementation on Sexual Function and Depression Symptoms of Women with Vitamin D Deficiency: A Randomized Controlled Trial

Protocol summary

Study aim

To determine the effect of Vitamin D supplementation on sexual function and depression symptoms in women with vitamin D deficiency (or insufficiency) and sexual dysfunction

Design

In this randomized triple-blind placebo-controlled trial (phase 3), 48 women with vitamin D deficiency and about 24 women with vitamin D insufficiency who have sexual dysfunction and no severe depression will be randomly allocated into intervention (receiving 4000 or 2000 IU oral vitamin D daily) or control (receiving placebo) groups using stratified (based on the use or non-use of hormonal contraceptive and minimal/mild depression or moderate depression) block randomization with block size of 4 and allocation ratio of 1:1. The intervention will last for 3 months.

Settings and conduct

Participants will be recruited among women covered by the randomly selected health centers in Tabriz, Iran. After primary assessment and receiving written informed consent, other eligibility criteria will be assessed using FSFI sexual function and Beck depression questionnaires and determining serum level of 25 hydroxy vitamin D. Eligible women will be randomized into groups receiving vitamin D or placebo. Participants, investigators, and statistical analyst will be blinded.

Participants/Inclusion and exclusion criteria

Married women aged 18-40 years with serum level of 25 hydroxy vitamin D less than 20 ng/ml in the vitamin D deficiency group and 20-30 ng/ml in the vitamin D insufficiency group, a score of 28 or less based on the FSFI, no severe depression

Intervention groups

For three months, in the group with vitamin D deficiency: 4000 IU/d vitamin D or placebo, and in the group with vitamin D insufficiency: one 2000 IU/d vitamin D capsule

or placebo

Main outcome variables

Sexual function score (FSFI); Beck depression score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100414003706N33**

Registration date: **2018-12-08, 1397/09/17**

Registration timing: **prospective**

Last update: **2018-12-08, 1397/09/17**

Update count: **0**

Registration date

2018-12-08, 1397/09/17

Registrant information

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

alizades@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-20, 1397/09/29

Expected recruitment end date

2019-05-19, 1398/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Vitamin D Supplementation on Sexual Function and Depression Symptoms of Women with Vitamin D Deficiency: A Randomized Controlled Trial

Public title

Effect of Vitamin D on Sexual Function and Depression of Women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Married women aged 18-40 years Educational level at minimum 6 years and ability to complete study questionnaires The serum level of 25-hydroxy vitamin D less than 20 ng/ml in the vitamin D deficiency group and 20-30 ng/ml in the vitamin D insufficiency group Impaired sexual function (a score of 28 or less based in the FSFI) Living with her husband in the last month and following three months

Exclusion criteria:

Unwillingness to participate in the study Pregnancy The first six months after delivery Severe depression based on Beck Depression Inventory Consumption of more than 50 000 IU vitamin D supplements during the past 3 months Drug and alcohol addiction of each of the couples Occurrence of any stressful event or important psychological problem in the last 6 months, according to participant report Taking any drug affecting serum levels of vitamin D (e.g. glucocorticoids, glycosides, thiazide diuretics, phenobarbital, phenytoin, cholestyramine, and calcium-vitamin D supplements) History of chronic diseases such as thyroid and pituitary diseases, according to participant report History of any cancer History of infertility Taking antidepressants or antipsychotics in the past 6 months Genital surgery Vaginal infection, according to participant report Premature menopause Husband major sexual function problems, according to woman report

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible women will be allocated into intervention and control groups separately based on serum level of vitamin D (deficiency or insufficiency) using stratified (based on use or non-use of hormonal contraceptive and minimal/mild depression or moderate depression) block randomization with block size of 4 and allocation ratio of 1:1. A computerized program (randomizer) will be used to generate the allocation sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

Vitamin D and placebo will be prepared by the pharmaceutical company in identical shape, color and smell. To conceal the sequence, the drugs (or corresponding placebo) will be placed inside a consecutively numbered sealed opaque envelopes. The sequence generation and preparation of the envelopes will be done by a person not involved in participant recruitment or data collection. Investigators, health care providers, outcome assessors, and statistical analyst will be blinded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Ave., Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2018-10-22, 1397/07/30

Ethics committee reference number

IR.TBZMED.REC.1397.620

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

Depression

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

Primary outcomes

1

Description

Sexual function score

Timepoint

At the baseline (before intervention) and just after completion of the intervention (3 months after initiation of the intervention)

Method of measurement

Using the FSFI questionnaire

2

Description

depression score

Timepoint

At the baseline (before intervention) and just after completion of the intervention (3 months after initiation of the intervention)

Method of measurement

Using the Beck Depression Inventory questionnaire

Secondary outcomes

1

Description

Side events

Timepoint

during 12 weeks after initiation of intervention

Method of measurement

self- report

2

Description

level of serum vitamin D

Timepoint

At the baseline (before intervention) and just after completion of the intervention (3 months after initiation of intervention)

Method of measurement

Measurement of serum vitamin D levels by kits using enzyme immunoassay

3

Description

Satisfaction from the intervention

Timepoint

At the end of the intervention

Method of measurement

Using 10 cm visual analogue scale

Intervention groups

1

Description

Intervention group 1 (women with vitamin D deficiency): Oral capsules of vitamin D3 4000 IU/d (one 4000 IU or two 2000 IU capsules) for 3 months, prepared by Dana pharmaceutical company.

Category

Treatment - Drugs

2

Description

Control group 1 (women with vitamin D deficiency, control for intervention group 1): Placebo oral capsules identical with vitamin D3 4000 IU/d, prepared by Dana pharmaceutical company, for 3 months.

Category

Treatment - Drugs

3

Description

Intervention group 2 (women with vitamin D insufficiency): One vitamin D3 capsule 2000 IU orally, prepared by Dana pharmaceutical company, once a day for 3 months.

Category

Treatment - Drugs

4

Description

Control group 2 (women with vitamin D insufficiency, control for intervention group 2): Placebo oral capsules identical with vitamin D3 2000 IU, prepared by Dana pharmaceutical company, once a day for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Public health centers in Tabriz

Full name of responsible person

Dr Mitra Yeghaneh

Street address

Nesfrah Sqre., Tabriz health center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Parishan Bahramy
Position
MSc student in midwifery
Latest degree

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Requested data will be provided to researchers for statistical analysis (meta- analysis) of the submitted proposal.

When the data will become available and for how long

starting immediately after publication of the study results

To whom data/document is available

Data will be available to researchers working at academic organizations, as well as to chief editor (and reviewers) of the journal of the submitted manuscript/s, if requested.

Under which criteria data/document could be used

The data will be available to researchers upon request and submission of a proposal to perform meta-analysis using IPD data after being unidentified. Also, in exceptional cases, data will be made available to journal of submitted manuscript/s for checking accuracy of the data.

From where data/document is obtainable

Refer to the email address (alizades@tbzmed.ac.ir)

What processes are involved for a request to access data/document

The requests will be sent by email and data will be available within a week.

Comments