Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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)

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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
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Sponsors / Funding sources

1

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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
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Professor

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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