Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Feb 2026

The effect of vitamin D supplements on sexual satisfaction, function and self-efficacy among women in reproductive age.

Protocol summary

Study aim
The effect of vitamin D supplements on sexual satisfaction, function and self-efficacy among women in reproductive age.

Design
People enter the study who have low sexual function and satisfaction, and without depression. The sample size was determined 102 people (51people in controls and 51 people in case group) were calculated by statistical consltant and based on the previous studies . people with deficiency vitamin D who are dysfuction sexual are identified and then separate envelopes are placed A and B are box (A case group and control group B), and each participant will takes an envelope, the case group will be taken 1 tablet of vit D 600 unit daily for 12 weeks and to the control group will be taken 1 tablet of placebo daily for 12 weeks, and after12 weeks, vitamin D level is measured.To sample are again the sexual satisfaction and sexual function and sexual self-efficacy questionnaires. After completing the questionnaires, the scores are compared with scores of before intervention .

Settings and conduct
The sample of the study is all women refered to health centers affiliated to Ahwaz jundishapur University of medical sciences who are eligible to enter study at the time of the research

Participants/Inclusion and exclusion criteria
Entry criteria: Married, women of reproductive age, having sex with a partner, vitamin D level less than 30 ng / ml, junior grade less than 55.26, sexual satisfaction score less than 100,Exit criteria: Menopause, pregnancy, history of chronic diseases such as blood pressure, diabetes and hypothyroidism, immune defenses, antihypertensive drugs and antidepressants, menstrual disorder, lactation, vaginal infections and cervicitis

Intervention groups
In the intervention group, using tablet of vitD In the control group using placebo

Main outcome variables
Sexual satisfaction, function and sexual self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180117038413N1**
Registration date: **2018-03-09, 1396/12/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-09, 1396/12/18**
Update count: **0**

Registration date
2018-03-09, 1396/12/18

Registrant information

Name
Naghme Ajeli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3379 6534

Email address
ajeli.n@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-28, 1396/12/09

Expected recruitment end date
2018-05-30, 1397/03/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of vitamin D supplements on sexual satisfaction, function and self-efficacy among women in reproductive age.

Public title
The effect of oral vitamin D supplementation on satisfaction, performance, and sexual self-efficacy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Being married Women of reproductive age 18 - 45 years Having sex with spouse Being a single wife Literacy reading and writing The level of vitamin D is less than 30 ng / ml Sexual performance score is less than 26/55 Sexual satisfaction score less than 100

Exclusion criteria:
Menopause Pregnancy History or presence of chronic diseases such as blood pressure and diabetes, hypothyroidism and immune disorders Antihypertensive drugs and antidepressants Taking antipsychotics over the past 6 months Hormone replacement therapy Or contraceptive pills Moderate and severe depression Vaginal and cervicitis infections The occurrence of a horrible event (death of loved ones, incidents with disabilities) Menstrual irregularities Lactation

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization will be done using random numbers And the coupled numbers obtained for group A the odds for group B are considered (Box A case group and box B control group)

Blinding (investigator's opinion)
Double blinded

Blinding description
Researcher and volunteer Participant in this study is completely unaware of the drug or placebo supplements, and this is done by the pharmacist in the same packages and then encoded

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethice committee of Ahvaz University of Medical Sciences

Street address
Golestan Highway

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2017-12-11, 1396/09/20

Ethics committee reference number
IR.AJUMS.REC.1396.812

Health conditions studied

1

Description of health condition studied
Disorder in sexual function and satisfaction ،

ICD-10 code

ICD-10 code description
sexual function

Primary outcomes

1

Description
Vit D

Timepoint
12 weeks

Method of measurement
Blood taking(before intervention and after intervention)

Secondary outcomes

1

Description
Sexual satisfaction

Timepoint
Before the intervention and 12 weeks after the intervention

Method of measurement
Larson questionnaire

2

Description
Sexual function

Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
FSFI questionnaire

3

Description
Sexual sell _ efficacy
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Sexual sell_ efficacy questionnaire

Intervention groups

1

Description
Intervention group: Tablet Vitamin D 600u daily for 12 weeks
Category
Treatment - Drugs

2

Description
Control group:Placebo,tablet 1 daily for 12 weeks Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Center No. 2 West
Full name of responsible person
Naghme Ajeli
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South Soroush Ave, Khashayar،Health Center No 2 of West Ahwaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Naghme Ajeli
Position
Student
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)
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
No - There is not 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