

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

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

Protocol summary

Sexual satisfaction, function and sexual self-efficacy

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 (51 people in controls and 51 people in case group) were calculated by statistical constant and based on the previous studies . people with deficiency vitamin D who are dysfunction 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 after 12 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 referred 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

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		Secondary ids	empty
Scientific title	The effect of vitamin D supplements on sexual satisfaction, function and self-efficacy among women in reproductive age.	Ethics committees	
Public title	The effect of oral vitamin D supplementation on satisfaction, performance, and sexual self-efficacy	1	
Purpose	Treatment	Ethics committee	
Inclusion/Exclusion criteria		Name of ethics committee	Ethics committee of Ahvaz University of Medical Sciences
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	Street address	Golestan Highway
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	City	Ahvaz
Age	From 18 years old to 45 years old	Province	Khouzestan
Gender	Female	Postal code	61357-15794
Phase	3	Approval date	2017-12-11, 1396/09/20
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor	Ethics committee reference number	IR.AJUMS.REC.1396.812
Sample size	Target sample size: 102	Health conditions studied	
Randomization (investigator's opinion)	Randomized	1	
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)	Description of health condition studied	Disorder in sexual function and satisfaction .
Blinding (investigator's opinion)	Double blinded	ICD-10 code	
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	ICD-10 code description	sexual function
Placebo	Used	Primary outcomes	
Assignment	Parallel	1	
Other design features		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 self _ efficacy

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

Sexual self _ 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

Street address

South Soroush Ave, Khashayar. Health Center No 2 of West Ahwaz

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

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Web page address**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

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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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