

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 take 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

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

Ethics committee of Ahvaz University of Medical Sciences

Street address

Golestan Highway

City

Ahvaz

Province

Khuzestan

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

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

Ahwaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badvi

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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

Ahwaz 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

Ahwaz 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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Educational coach

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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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