Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of vitamin D supplementation compared with the placebo on changing of sexual function in vitamin D-deficient women

Protocol summary

Summary

This study is a double blind randomized clinical trial to determine the effect of vitamin D administration compared with the placebo on sexual function in vitamin D-deficient women. 100 women, aged 18 to 45 years old with 25-(OH)D < 25 ng/ml, who were eligible for this study were recruited from selected healthcare centers in Tehran. Informed consent form was completed by each participant at the beginning of this single center study. Participants will be divided in two groups randomly. At first, both groups were educated about the normal sexual response. Participants in the intervention group, received two 300000IU vitamin D ampoules and in control group received two placebo contained with distilled water ampoules 4-week intervals. Depression grade at baseline and end of week 8 was evaluated by Beck questionnaire. At the beginning and end of week 8, serum 25(OH)-D3 was measured. Also, sexual function was assessed by FSFI questionnaire.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201608053860N28**
Registration date: **2016-11-06, 1395/08/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-11-06, 1395/08/16

Registrant information

Name

Gity Ozgoli

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2512

Email address

gozgoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Nursing and Midwifery College, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-02-14, 1394/11/25

Expected recruitment end date

2016-08-19, 1395/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation compared with the placebo on changing of sexual function in vitamin D-deficient women

Public title

The effect of vitamin D on sexual function in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Aged 18 to 45 years old; 25(OH) D<30 ng/ml; Women must be without following diseases: hypothyroidism; hyperprolactinemia; liver diseases; and vaginal infection; Lack of stressful event during the past 6 months; Lack of mental problems; Without alcohol or drug addiction; Voluntary participitation. Exclusion criteria: Taking any drug or supplement that interfere

with sexual function; Getting pregnant; Migration.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization and Blinding: Participants will allocated randomly using a random number table; for this, a study leader who is not involve in study protocol will create the randomization list assigning participants to the vitamin D or the placebo group. Two vitamin D or placebo ampuls were provided for each participant and in order to two administration with 4-week interval. The study leader labeled these ampuls with participant numbers using the randomization list. Thus, none of investigator and participants had not any information about the type of groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Nursing and Midwifery College, Shahid Beheshti University of Medical Sciences

Street address

Valiasr St, Niayesh Junc

City

Tehran

Postal code

1985717443

Approval date

2016-03-01, 1394/12/11

Ethics committee reference number

IR.SBMU.PHNM.343.1394

Health conditions studied

1

Description of health condition studied

Sexual dysfunction

ICD-10 code

F52

ICD-10 code description

dysfunction-sexual(due to)-lack-or loss of sexual desive

Primary outcomes

1

Description

Sexual function

Timepoint

Before the intervention and then 4 and 8 weeks after the intervention

Method of measurement

FSFI questionnaire

Secondary outcomes

1

Description

Depression

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Beck Depression questionnaire

Intervention groups

1

Description

Intervention group: Injection two 300000IU vitamin D ampoule; Iran Hormone; made in Iran; at baseline and end of week 4

Category

Treatment - Drugs

2

Description

Control group: Injection two water distilled ampoule ; Soha; made in Iran; at baseline and end of week 4

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasol Akram Hospital

Full name of responsible person

Fatemeh Jalali Chimeh

Street address

Mansori St, Niayesh Ave, Shahrara Ave, Tehran
City
Tehran

2

Recruitment center
Name of recruitment center
Firozgar Hospital
Full name of responsible person
Fatemeh Jalali Chimeh
Street address
Behafarin St, Karimkhan Ave, Valiasr Sq
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research, Nursing and Midwifery College, Shahid Beheshti University of Medical Sc
Full name of responsible person
Dr.Mahrokh Dolatian
Street address
Vice Chancellor of Research, Nursing and Midwifery College, Shahid Beheshti University of Medical Sciences, Valiasr St, Niayesh Junc
City
Tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research, Nursing and Midwifery College, Shahid Beheshti University of Medical Sc
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Nursing and Midwifery College, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fatemeh Jalali Chimeh
Position
Graduate Student Of Midwifery
Other areas of specialty/work
Street address
Nursing and Midwifery College of Shahid Beheshti University of Medical Sciences, Valiasr St, Niayesh Junc, Tehran
City
Tehran
Postal code
1985717443
Phone
+98 22523373
Fax
Email
fatemehjalali_ch@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Nursing and Midwifery College, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Gity Ozgoli
Position
Assistant professor
Other areas of specialty/work
Street address
Nursing and Midwifery College of Shahid Beheshti University of Medical Sciences, Valiasr St, Niayesh Junc, Tehran
City
Tehran
Postal code
1985717443
Phone
+98 21 8820 2521
Fax
+98 21 2219 0684
Email
gozgoli@yahoo.com
Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code

empty

Data Dictionary

empty