

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 participation. 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

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### 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

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#### Phone

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#### Email

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#### 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*