

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Vitamin D supplement on quality of life, lipid profile and C - reactive protein among women with cyclical mastalgia

#### Protocol summary

##### Summary

The aims of the present study are to examine the effect of vitamin D supplementation on quality of life, blood lipid profile and C- reactive protein. This clinical trial is conducted on 80 women suffering from cyclical mastalgia. They are randomly (through block randomization) allocated into the two study groups of vitamin D and placebo. The data collectors and participants will be kept blind to group allocation to create a double blind trial. This study will be conducted in the three centers affiliated to Shiraz University of Medical Sciences. The inclusion criteria include: having mastalgia for at least 5 days per menstrual cycle, vitamin D level between 10-30 Nano gram per milliliter, without any severe somatic or psychological disease, and no history of breast cancer. The vitamin D group will receive 2000 International Unit (IU) vitamin D per day for 8 weeks, whereas the control group will receive placebo. All women with serum vitamin D less than 10 ng/ml (severe deficiency) will receive 2000 IU vitamin D per day for 8 weeks. Their before and after intervention data will be compared at the end of the study. Stressful life events such as a family member death or starting a new program such as an exercise program or a new diet in daily life will lead to drop out from the study. The quality of life is measured before and after intervention in all participants. Also, vitamin D, lipid profiles and C- reactive protein of blood will be measured two times, before and after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017090210327N17**

Registration date: **2017-10-16, 1396/07/24**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-10-16, 1396/07/24

##### Registrant information

###### Name

Farideh Vaziri

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1627 9131

###### Email address

vazirif@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Shiraz University of Medical Sciences

##### Expected recruitment start date

2017-10-07, 1396/07/15

##### Expected recruitment end date

2018-03-20, 1396/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Vitamin D supplement on quality of life, lipid profile and C - reactive protein among women with cyclical mastalgia

##### Public title

Effect of vitamin D supplement on quality of life and some blood biochemical factors in women with breast

pain

### **Purpose**

Other

### **Inclusion/Exclusion criteria**

Inclusion criteria: At least 18 years of age; serum level of vitamin D 10- 30 ng/ ml; breast pain duration of  $\geq 5$  days per menstrual cycle; without any somatic or psychological disease. Exclusion criteria : Pregnant or lactating women; history of breast cancer; Stressful life events such as death of a family member.

### **Age**

From **18 years** old

### **Gender**

Female

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **80**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

The block randomization method is designed to randomize subjects into study groups.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

##### **Street address**

Zand street

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2017-07-30, 1396/05/08

#### **Ethics committee reference number**

IR.SUMS.REC.1396.92

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Vitamin D deficiency

### **ICD-10 code**

E55.9

### **ICD-10 code description**

Avitaminosis D

## **Primary outcomes**

### 1

#### **Description**

Change in quality of life

#### **Timepoint**

Before and after intervention

#### **Method of measurement**

Quality of life questionnaire

### 2

#### **Description**

Change in lipid profile

#### **Timepoint**

Before and after intervention

#### **Method of measurement**

Lab test

### 3

#### **Description**

Change in C- Reactive protein

#### **Timepoint**

Before and after intervention

#### **Method of measurement**

Lab test

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: This group will receive 2000 IU of oral vitamin D per day for 8 weeks.

#### **Category**

Other

### 2

#### **Description**

Control group: The control group will receive placebo for 8 weeks.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

**Name of recruitment center**

Breast clinic in Motahari medical center

**Full name of responsible person**

Soheila Shafieian

**Street address**

Nemazi square

**City**

Shiraz

**Email**

roose82003@yahoo.com; vazirif@sums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Hoseien Dabbaghmanesh

**Position**

Endocrinologist

**Other areas of specialty/work****Street address**

Densitometry center, Nemazi hospital, Zand street

**City**

Shiraz

**Postal code****Phone**

+98 71136281497

**Fax****Email**

dabbaghm@sums.ac.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research of Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Basir Hashemi

**Street address**

Zand street

**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Shiraz University of Medical Sciences

**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farideh Vaziri

**Position**

MS degree

**Other areas of specialty/work****Street address**

Nursing and Midwifery school, Nemazi square, Zand street

**City**

Shiraz

**Postal code****Phone**

+98 71136281497

**Fax****Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farideh Vaziri

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MS degree

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**Fax****Email**

vazirif@sums.ac.ir

**Web page address****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*