

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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 ≥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

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**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