

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of the effect of Vitamin D supplementation on pain and serum level of prolactin in women suffering from cyclical mastalgia

Protocol summary

Summary

The aims of the present study are to examine the effect of vitamin D supplementation on intensity of cyclical breast pain and prolactin level. 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 intensity of breast pain is measured before and after intervention in all participants by visual analogue scale (VAS). Also, vitamin D and prolactin levels will be measured two times, before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072610327N16**

Registration date: **2017-08-26, 1396/06/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-26, 1396/06/04

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

Shiraz University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Vitamin D supplementation on pain and serum level of prolactin in women suffering from cyclical mastalgia

Public title

Vitamin D supplementation effect on cyclical mastalgia

Purpose

Treatment

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

No age limit

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

2017-05-27, 1396/03/06

Ethics committee reference number

IR.SUMS.REC.1396.31

Health conditions studied

1

Description of health condition studied

Cyclical mastalgia

ICD-10 code

N64.4

ICD-10 code description

Mastodynia

Primary outcomes

1

Description

Intensity of mastalgia

Timepoint

before and after intervention

Method of measurement

Visual analogue scale (VAS)

2

Description

Serum level of prolactin

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

N/A

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

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**

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Mohammad Hoseien Dabbaghmanesh

Position

Endocrinologist

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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