

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of vitamin D supplementation on the reduction of painful symptoms in women with endometriosis: a randomized controlled trial

Protocol summary

Study aim

To determine the effect of vitamin D on the painful symptoms of endometriosis

Design

A clinical trial with a control group, parallel groups, triple-blind, randomized, phase 3 on 66 patients. The stratified random block method was used for randomization.

Settings and conduct

This study will be conducted on women with endometriosis at Al-Zahra Educational Center-Tabriz. The intervention group will be given vitamin D tablets with a dose of 4000 mg and the control group will be given a placebo with the same dose every other day for eight weeks. An envelope containing the drug (vitamin D or placebo) will be prepared for each participant; they will be reminded that the next follow-up will be eight weeks later. The participants will be contacted once a week and will be reminded to take the medication; they will be asked to check the medication intake checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with endometriosis. Exclusion criteria: Patients with systemic diseases such as diabetes and high blood pressure.

Intervention groups

Vitamin D tablets with a dose of 4000 mg for the intervention group and the placebo with the same dose for the control group will be given every other day for eight weeks.

Main outcome variables

Mean score of painful symptoms of endometriosis 8 weeks after starting the treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N78**

Registration date: **2023-05-25, 1402/03/04**

Registration timing: **prospective**

Last update: **2023-05-25, 1402/03/04**

Update count: **0**

Registration date

2023-05-25, 1402/03/04

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-31, 1402/03/10

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin D supplementation on the reduction of painful symptoms in women with endometriosis: a randomized controlled trial

Public title

Effect of vitamin D in the treatment of endometriosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women who have endometriosis and it has been confirmed by laparoscopy. Women with symptomatic endometriosis. Women who are married and sexually active. Vitamin D serum level should be less than 30 ng/dl.

Exclusion criteria:

Patients with diabetes, thyroid disorders, high blood pressure, hyperprolactinemia and Cushing's syndrome
Daily and regular consumption of supplements containing vitamin D during the last three months

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: 66

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be randomly classified by the block method based on the computer program of Random Allocation (stratification based on vitamin D level; lack or insufficient) with a block size of four and six and a ratio of 1:1 allocation into intervention (vitamin D) and control groups (placebo).

Blinding (investigator's opinion)

Triple blinded

Blinding description

People involved in sample selection, data collection, analysis, and the participants will be blinded. Vitamin D and placebo will be prepared by Dana Pharmaceutical Company in a completely similar way in terms of appearance; the usage method will be the same.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

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Tabriz

Province

East Azarbaijan

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5138947977

Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

IR.TBZMED.REC.1402.109

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Mean score of painful symptoms of endometriosis

Timepoint

Before intervention and 8 weeks after the start of treatment

Method of measurement

Menstrual painful symptoms questionnaire (ENDOPAIN-4D)

Secondary outcomes

1

Description

Quality of lifemean score

Timepoint

Before intervention and 8 weeks after the start of treatment

Method of measurement

Endometriosis Health Profile-30

2

Description

Average severity of dysmenorrhea

Timepoint

Before intervention and 8 weeks after the start of treatment

Method of measurement

Visual Analog Scale

3

Description

The frequency of Gelofen consumption

Timepoint

During the treatment

Method of measurement

Checklist

4

Description

Adverse events

Timepoint

During the treatment

Method of measurement

Checklist

Intervention groups

1

Description

The intervention group will receive oral vitamin D tablets with a dose of 4000 mg every other day for eight weeks, which will be prepared by Dana Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

The control group will receive oral placebo tablets similar to vitamin D tablets (4000 mg) every other day for eight weeks, which will be prepared by Dana Pharmaceutical Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra educational hospital

Full name of responsible person

Mojgan Mirghafourvand

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Baghshomal Square, Al-Zahra educational hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Mirghafourvand

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of participants' information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available