Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone
+98 41 1479 6969

Email address
mirghafourvandm@tbzmed.ac.ir

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
City
Tabriz
Province
East Azarbaijan
Postal code
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
Street address
Baghshomal Square, Al-Zahra educational hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6770
Email
nursing@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
Street address
Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3334 4280
Email
research-vice@tbzmed.ac.ir
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
Street address
Faculty of Nursing and Midwifery, South Shariati street, Tabriz
City
Tabriz
Province
East Azarbaijan

Postal code
5138947977
Phone
+98 41 3479 6770
Email
mirghafourvand@gmail.com

Person responsible for scientific 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
Street address
Faculty of Nursing and Midwifery, South Shariati street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6770
Email
mirghafourvand@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mojgan Mirghafourvand
Position
Professor
Latest degree
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Other areas of specialty/work
Reproductive Health
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+98 41 3479 6770
Email
mirghafourvand@gmail.com

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