Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Study of the effect of vitamin D supplementation on clinical symptoms, parameters of mental health, metabolic profiles, inflammatory factors and biomarkers of oxidative stress in patients with endometriosis

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of vitamin D supplementation on clinical symptoms, parameters of mental health, metabolic profiles, inflammatory factors and biomarkers of oxidative stress in patients with endometriosis.

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive either vitamin D supplement (n=30) or placebo (n=30).

Settings and conduct

Among patients with endometriosis referred to gynecology and obstetric Clinic affiliated to Iran University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with endometriosis aged 18-40. Exclusion criteria: Diabetes mellitus, Thyroid disorders, Hypertension, Hyperprolactinemia, Cushing syndrome.

Intervention groups

Intervention group: 50000 IU vitamin D biweekly (Zahravi, Tabriz, Iran), for 12 weeks orally. Control group: vitamin D placebo (Barij essence, Kashan, Iran), every 2 weeks, for 12 weeks orally.

Main outcome variables

Outcomes: malondialdehyde (primary outcome) and clinical status, mental health status, inflammatory factors, markers of insulin metabolism, lipid profile (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N60**
Registration date: **2019-06-15, 1398/03/25**
Registration timing: **retrospective**

Last update: **2019-06-15, 1398/03/25**
Update count: **0**

Registration date

2019-06-15, 1398/03/25

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5546 3378

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-08, 1398/01/19

Expected recruitment end date

2019-05-09, 1398/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Study of the effect of vitamin D supplementation on clinical symptoms, parameters of mental health, metabolic profiles, inflammatory factors and biomarkers of oxidative stress in patients with endometriosis

Public title
The effect of vitamin D supplementation in treatment of endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
women with endometriosis Individuals aged 18-40
Exclusion criteria:
Diabetes mellitus Thyroid disorders Hypertension Hyperprolactinemia Cushing syndrome

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m2) and age (<30 and ≥30 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the gynecology clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Shahid Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1771844351

Approval date
2019-04-07, 1398/01/18

Ethics committee reference number
IR.IUMS.REC.1398.129

Health conditions studied

1

Description of health condition studied
Endometriosis

ICD-10 code
N80

ICD-10 code description
Endometriosis

Primary outcomes

1

Description
Malondialdehyde

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Spectrophotometry

Secondary outcomes

1

Description
Dyspareunia

Timepoint
At the beginning of the study and after 12 weeks of intervention

Method of measurement
Questionnaire

2

Description
dysmenorrhea

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

3

Description

dysuria

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

4

Description

Pelvic pain

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

5

Description

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

6

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

7

Description

Beck depression questionnaire

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

8

Description

General health questionnaire

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

9

Description

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

10

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

11

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

12

Description

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Calculation using HOMA formula

13

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

14

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

15

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Intervention group: 50000 IU vitamin D biweekly (Zahravi, Tabriz, Iran), for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: vitamin D placebo (Barij essence, Kashan, Iran), every 2 weeks, for 12 weeks orally.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram Hospital
Full name of responsible person
Dr. Mansooreh Samimi
Street address
Satarkhan St, Rasoul Akram Hospital
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1771844352
Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Kazem Malakouti
Street address
Hemat Highway, DescriptionIran University of Medical Sciences
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Tehran
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Tehran
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1881966542
Phone
+98 21 8670 1021
Email
malakouti@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available