

# 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)

##### Phone

+98 31 5546 3378

##### Email address

ostadmohammadi-vr@kaums.ac.ir

##### 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  $\geq 25$  kg/m<sup>2</sup>) and age (<30 and  $\geq 30$  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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Tehran

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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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#### Province

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#### Phone

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#### 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

Nutrition

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##### Province

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##### Web page address

## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Latest degree**  
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**Other areas of specialty/work**  
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**Web page address**

## 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