

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Investigating the effect of Citalopram (selective serotonin reuptake inhibitor) on the symptoms of endometriosis patients under medical treatment

#### Protocol summary

##### Study aim

Investigating the effect of Citalopram on the symptoms of endometriosis patients under medical treatment

##### Design

Clinical trial(pilot) with a control group, with parallel groups, Triple -blind, randomized, phase3 on 80patients. Block random allocation method will be done using the website: [www.sealedenvelope.com](http://www.sealedenvelope.com).

##### Settings and conduct

Based on the block randomization list, they are randomly assigned to two groups of patients referring to Arash Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Symptomatic patients with endometriosis; under medical treatment; aged 18 to 45 years; no desire for pregnancy. Exclusion criteria: pregnancy; lactation; abnormal findings against endometriosis; indication for surgery; drug intolerance; SSRIs contraindications.

##### Intervention groups

In the placebo group, one 2 mg Verogest tablet(AntiPharmed Company ) daily starts from the 10th day of the first menstrual period along with 2 placebo tablets after the baseline visit for 12 weeks. control group :was prescribed 1 tablets of Citalopram 20mg daily(Sobhan Company) along with Verogest 2 mg in the same way as the first group.

##### Main outcome variables

Dysmenorrhea; dyspareunia; dyschezia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180211038692N2**  
Registration date: **2023-10-26, 1402/08/04**

Registration timing: **prospective**

Last update: **2023-10-26, 1402/08/04**

Update count: **0**

##### Registration date

2023-10-26, 1402/08/04

##### Registrant information

###### Name

Samira Mirzaei

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3330 2171

###### Email address

[samira.mirzaei.dr@gmail.com](mailto:samira.mirzaei.dr@gmail.com)

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-03, 1402/08/12

##### Expected recruitment end date

2024-02-04, 1402/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of Citalopram (selective serotonin reuptake inhibitor) on the symptoms of endometriosis patients under medical treatment

##### Public title

Effect of Citalopram on Endometriosis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Symptomatic patients with endometriosis under medical treatment age between 18 till 45 no desire for pregnancy

### Exclusion criteria:

pregnancy lactation abnormal findings against endometriosis indication for surgery drug intolerance SSRIs contraindications

## Age

From **18 years** old to **45 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Our sample size is 80 people, with 30 people in each group. The unit of study is the individual. We will use the block randomization method by using: [www.sealedenvelope.com](http://www.sealedenvelope.com). The number of blocks considered is 4

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

The list of random allocation of patients is only at the disposal of the clinic nurse. In order to hide the random allocation process, the sequence of treatments will be written on 80 cards in order. Then the cards will be placed inside sealed envelopes. When the doctor qualifies the patient to enter Determined for the study, the nurse provides the doctor with the envelope related to the type of intervention. In order to check the outcome, a doctor who was unaware of the type of intervention is used. Also, for data analysis, a statistician who is separate from the study process and from all The procedures performed are used in an uninformed manner. The study is triple-blind. The patient is also unaware.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Tehran University of Medical Science

#### Street address

Qods street , Keshavarz Bulevar, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1417653761

### Approval date

2023-07-16, 1402/04/25

### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.239

## Health conditions studied

## 1

### Description of health condition studied

Endometriosis

### ICD-10 code

N80

### ICD-10 code description

Endometriosis

## Primary outcomes

## 1

### Description

درد هنگام نزدیکی

### Timepoint

Before and 3 months after treatment starting

### Method of measurement

Visual analogous scale

## 2

### Description

Dysmenorrhea

### Timepoint

Before and 3 months after treatment starting

### Method of measurement

Visual analogous scale

## 3

### Description

Dyschezia

### Timepoint

Visual analogous scale

### Method of measurement

Visual analogous scale

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Patients use 1 tablet of Citalopram 20mg(Sobhan Company) and one tablet of Verogest 2 mg (Ati Pharmed Company) daily for up to 3 months continuously

### Category

Treatment - Drugs

2

### Description

Control group: Patients use 1 tablet of placebo and one tablet of Verogest 2 mg (Ati Pharmed Company) daily for up to 3 months continuously.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Arash women's hospital

#### Full name of responsible person

Dr. Reyhaneh Hoseini

#### Street address

No.162 Alley (Abdul Majid ) , Shahid Baghdarnia Street ( North Rashid ),Shahid Bagheri Haghway ,Resalat Highway , Tehran , Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

1653915981

#### Phone

+98 21 7788 3283

#### Fax

+98 21 7788 3196

#### Email

rayh\_h@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr Akbar Fotouhi

#### Street address

Central University, Qods St, Keshavarz Blv,

#### City

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#### Province

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#### Postal code

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#### Phone

+98 21 8163 3619

#### Fax

+98 21 8163 3611

#### Email

rmo@tums.ac.ir

#### Web page address

http://vcr.tums.ac.ir/

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

#### Full name of responsible person

Dr.Reyhaneh.Hosseini

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse,Tehran.Iran

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#### Province

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#### Postal code

1653915981

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+98 21 7771 9922

#### Email

r-hosseini@tums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

**Full name of responsible person**

Reyhaneh hosseini

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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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

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Reyhaneh hosseini

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**