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.

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)

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+98 41 3330 2171

Email address
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 is80 people, with 30people in each group.The unit of study is the individual. We will use the block randomization method by using: 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 on80 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
دردهنگام 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
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Sponsors / Funding sources

1

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Name of organization / entity
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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
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Other areas of specialty/work
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Person responsible for updating data

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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