Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of valproic acid and dienogest in reducing endometriosis symptoms in patients with endometriosis

Protocol summary

Study aim
Providing scientific evidence for selecting more effective treatment in the management of endometriosis

Design
A Phase 1-2, randomized, triple-blind, parallel-group, controlled clinical trial involving 120 patients. Random allocation will be performed using permuted blocks via the Random Allocation software.

Settings and conduct
This study is being conducted on patients with endometriosis presenting to the Mother and Child Hospital in Shiraz. Participants will be randomly assigned to two groups: Group A (receiving 2 mg Dienogest tablets) and Group B (receiving 500 mg Valproic acid tablets). Six months after the initiation of treatment, the reduction in endometriosis symptoms will be compared between the two groups. The study employs a triple-blind design; the patients, the researchers, and the outcome assessors remain blinded to the group assignments (Group A or Group B).

Participants/Inclusion and exclusion criteria
Inclusion Criteria • Women with a definitive diagnosis of endometriosis • No prior pharmacological treatment for endometriosis before the start of the study • No use of similar pharmacological treatments (dienogest or valproic acid) within the past three months • No known history of allergy or hypersensitivity to the medications Exclusion Criteria • Pregnancy or intention to become pregnant during the six-month treatment period • Presence of coagulation disorders or a history of thrombosis

Intervention groups
Treatment group A will receive one 2 mg dienogest tablet daily (morning and evening) for 6 consecutive months. Treatment group B will receive two 500 mg valproic acid tablets daily (morning and evening) for 6 consecutive months.

Main outcome variables
The primary outcome is the severity of endometriosis-associated pelvic pain, which will be measured—prior to treatment, as well as 3 and 6 months after the initiation of treatment—using the Visual Analogue Scale (VAS).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240109060656N8**
Registration date: **2026-11-04, 1405/08/13**
Registration timing: **prospective**

Last update: **2026-11-04, 1405/08/13**
Update count: **0**

Registration date
2026-11-04, 1405/08/13

Registrant information

Name
Mojtaba Neydavoodi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3230 5410

Email address
neydavodi41@gmail.com

Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-11-22, 1405/09/01

Expected recruitment end date
2026-12-21, 1405/09/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of valproic acid and dienogest in reducing endometriosis symptoms in patients with endometriosis

Public title

Comparison of the effectiveness of valproic acid and dienogest in reducing endometriosis symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with a definitive diagnosis of endometriosis They must not have received any pharmacological treatment for endometriosis prior to the start of the study. Absence of similar pharmacological treatment (dienogest or valproic acid) over the past three months No history of known allergy or hypersensitivity to medications

Exclusion criteria:

Pregnancy or the intention to become pregnant during the six-month treatment period Presence of coagulation disorders or prior thrombosis

Age

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

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using the "Random Allocation" software, employing a permuted-block randomization method. Specifically, various blocks of four (such as ABBA, BABA, ABAB, BBAA, AABB, and BABA) will be generated; one of these blocks will be randomly selected, and patients will be assigned to either Group A or Group B based on the sequence specified within the chosen block.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be conducted as a triple-blind trial. In this study, patients will receive medications in packages coded as 'A' or 'B' and will remain unaware of the specific treatment they are receiving. The researcher will also be blinded to the treatment administered; they will provide the medication to patients in packages prepared by a collaborating pharmacist, with only the codes 'A' or 'B' marked on the packaging. Finally, the radiologist responsible for evaluating the findings from the patients' transvaginal ultrasound or pelvic MRI will also be unaware of the treatment the patients received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Specialized Committee on Ethics in Biomedical Research

Street address

Shiraz, Zand Street, Imam Hossein Square, Shiraz Faculty of Medicine

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2026-06-20, 1405/03/30

Ethics committee reference number

IR.SUMS.MED.REC.1405.134

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Severity of pelvic pain associated with endometriosis

Timepoint

Measurements will be taken at baseline, and at 3 and 6 months after the start of treatment.

Method of measurement

Pain intensity will be measured using the Visual Analogue Scale (VAS).

Secondary outcomes

1

Description
Quality of Life in Patients with Endometriosis
Timepoint
6 months after starting treatment
Method of measurement
Quality of Life Questionnaire for Patients with Endometriosis (EHP-30)

Intervention groups

1

Description
Intervention group: Group A will receive one 2 mg dienogest tablet daily—in the morning and evening—for 6 consecutive months.
Category
Treatment - Drugs

2

Description
Intervention group: Group B will receive two 500 mg valproic acid tablets daily (in the morning and evening) for 6 consecutive months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghadir Mother and Child Hospital
Full name of responsible person
Shamim Shahab
Street address
Shiraz, past Darvazeh Quran, at the beginning of Golshan township: Ghadir Mother and Child Hospital.
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7144995377
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neydavodi41@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
Street address
Shiraz, Zand Street, opposite Palestine Street, Shiraz University of Medical Sciences Central Building
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7134814336
Phone
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Email
mohammadi219@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Shamim Shahab
Position
Obstetrics and Gynecology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific

inquiries

Contact

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Person responsible for updating data

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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
Given that the Vice-Chancellery for Research at Shiraz University of Medical Sciences is the funding body for this research project, any dissemination of information or findings related to the project must be carried out with the consent of the Vice-Chancellery.

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