Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Dienogest and continuous Combined Oral Contraceptive(COC) in reduction of pelvic pain in endometriosis

Protocol summary

Study aim
Comparison of the effect of Dienogest and continuous Combined Oral Contraceptive(COC) in reduction of pelvic pain

Design
Clinical trial on two groups, with parallel groups, on 126 patients, manual randomization. Easy sampling

Settings and conduct
study is conducted on women referring to Endometriosis Center at Taleghani University Hospital to investigate a more effective drug for reducing pain caused by endometriosis. patients were entered into study by easy sampling and randomized block into 26 groups of 5 and placed in two groups of taking Verogest and continuous oral contraceptive pills. first group is treated with Verogest 2 mg tablets every night for 180 days and the second group is treated with oral contraceptive pills containing 03.0 micrograms of ethinyl estradiol and 2 mg dinogest every night an effective drug for 180 days. Then, on 30th day, 90th day, and 180th day, patients are evaluated in terms of amount of pain reduction.

Participants/Inclusion and exclusion criteria
inclusion conditions: Women in between 18 to 45 years who are known to have endometriosis and diagnosed with endometriosis radiologically by a skilled sonographer, with endometriosis mapping sonography or MRI or have been confirmed by surgery and mention symptom of moderate to severe pelvic pain. exclusion criteria: presence of symptoms related to pelvic infections Pap smear or abnormal pelvic pathology contraindications to the use of hormonal drugs pregnancy

Intervention groups
people with endometriosis are divided into two groups, and one group is treated with Verogest and other group is treated with oral contraceptives, and reduction of pelvic pain in these two groups is investigated.

Main outcome variables
severity of pelvic pain caused by endometriosis, including dysmenorrhea and dyspareunia, and chronic pelvic pain.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241010063323N1**
Registration date: **2025-10-26, 1404/08/04**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-26, 1404/08/04**
Update count: **0**

Registration date
2025-10-26, 1404/08/04

Registrant information

Name
Aida Mazloomi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 917 301 6106

Email address
idaluxurious@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-22, 1404/03/01

Expected recruitment end date
2025-12-21, 1404/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Dienogest and continuous Combined Oral Contraceptive(COC) in reduction of pelvic pain in endometriosis

Public title
effect of Dienogest in reduction of pelvic pain in endometriosis; continuous Combined Oral Contraceptive(COC) in pelvic pain of endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
known case of endometriosis, and the diagnosis of endometriosis disease has been radiologically confirmed by the center's skilled sonographer with endometriosis mapping sonography or MRI or by surgery. Symptoms of pelvic pain are mentioned as moderate to severe. Women in the age group of 18 to 45 years

Exclusion criteria:
The presence of symptoms related to pelvic infections GNRH agonist use in the past 3 months Pap smear or abnormal pelvic pathology The presence of contraindications to the use of hormonal drugs Desire to become pregnant within the next four months Presence of surgical indication for endometriosis in the patient Use of hormonal drugs in the past month

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research, simple randomization is done with the help of a table of random numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti Medical University

Street address
Eerabi avenue, Taleghani hospital

City
Tehran

Province
Tehran

Postal code
1985717413

Approval date
2024-08-21, 1403/05/31

Ethics committee reference number
IR.SBMU.MSP.REC.1403.292

Health conditions studied

1

Description of health condition studied
endometriosis

ICD-10 code
N80

ICD-10 code description
Endometriosis

Primary outcomes

1

Description
endometriosis related pelvic pain

Timepoint
To assess the level of pelvic pain caused by endometriosis at the beginning of the study and 30, 90, and 180 days later

Method of measurement
verbal rating scale and visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group is treated with 2 mg of Verogest, one tablet every night for 180 days without forgetting.

Category
Treatment - Drugs

2

Description
Intervention group: The second group is treated with an

oral contraceptive pill containing 0.03 micrograms of ethinyl estradiol and 2 mg of dienogest, one effective pill every night without forgetting for 180 days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani hospital

Full name of responsible person
Aida Mazloomi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Aida Mazloomi

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Shared files: Participant data file, study protocol, statistical analysis map, informed consent form, clinical study report, codes used in analysis and data classification system. All data can be shared after de-identification.
When the data will become available and for how long
Access period starts 6 months after results are published
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
In order to use the data in therapeutic work and also to conduct further studies
From where data/document is obtainable
Applicants should visit the following email address to receive data: idaluxurious@gmail.com
What processes are involved for a request to access data/document
Applicants should visit the following email address to receive data: idaluxurious@gmail.com Applicants must first provide information about their research field and the purpose for which they want these files, and after review by me, if deemed appropriate, the files will be made available to the applicant.
Comments