Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative study of the effect of Dienogest and OCP on endometriosis-related pain and endometrioma size

Protocol summary

Study aim
A comparative study of the effect of dienogest and OCP on pain associated with endometriosis

Design
A clinical trial with parallel groups without blinding and randomized, phase 3 on 100 patients. Random number generation program will be used for randomization.

Settings and conduct
This clinical trial study will be conducted in Isfahan city at Al-Zahra Hospital on patients diagnosed with endometriosis. The way of working is dividing the patients into two treatment groups and treating them with LD or Dinogest daily for 1 year. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria
This study will be conducted on a group of women with a definitive diagnosis of endometriosis. The entry criteria include a definitive diagnosis of endometriosis in ultrasound and informed consent, and the criteria for not entering pregnancy intention and lack of informed consent.

Intervention groups
Patients in this study are divided into two groups. The first group is treated with Dynogest 2 mg tablets made by Aburihan Pharmaceutical Company on a daily basis and once a day for up to 1 year, and the second group is treated with LD tablets made by Aburihan Company on a cyclical basis for up to 1 year and 1 tablet each day.

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230509058136N1**
Registration date: **2023-05-11, 1402/02/21**
Registration timing: **prospective**
Last update: **2023-05-11, 1402/02/21**
Update count: **0**

Registration date
2023-05-11, 1402/02/21

Registrant information

Name
Niloofar Ashtari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3267 7354

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ashtarimedical@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effect of Dienogest and OCP on endometriosis-related pain and endometrioma size

Public title
Dienogest and OCPs on endometriosis-related pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age 16 to 40 sonography indicating endometriosis

informed consent no intention of pregnancy

Exclusion criteria:

intention of pregnancy without informed consent

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done with the help of random number generation program. A number of envelopes were determined according to the number of people in the study, and each sequence of numbers created by the program was placed in each envelope and the envelopes were closed. Then an envelope was opened according to the order of entry of the participants and the number inside was shown. If the production number is odd, the patient is placed in the first group, and if the number is even, the patient is placed in the second group.

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 Isfahan University of Medical Sciences

Street address

Hezar Jarib

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2022-06-01, 1401/03/11

Ethics committee reference number

IR.MUI.MED.REC.1401.224

Health conditions studied

1

Description of health condition studied

ENDOMETRIOSIS

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

pain

Timepoint

3 month, 6 month and 12 month after

Method of measurement

visual analoug scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment with Dienogest 2 mg tablets made by Aburihan company one per day and daily for up to 1 year.

Category

Treatment - Drugs

2

Description

Intervention group: Treatment with LD drug made by Aburihan company on a daily basis and once a day for up to 1 year

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Niloofar Ashtari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Saghayegh Haghjoo

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vcr-office@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Niloofar Ashtari

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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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
no more information
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