Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Sep 2026

The comparison of treatment with dienogest and contraceptive oral pills on the improvement of pain, and quality of life in surgery patients with advanced endometriosis

Protocol summary

Study aim

The comparison of treatment with dienogest and contraceptive oral pills on the pain and quality of life in surgery patients with advanced endometriosis

Design

This study will perform before and after the surgical procedure in three groups of patients with advanced endometriosis who will receive dienogest and contraceptive pills after surgery. Participants will be randomly assigned to three groups (two intervention groups and a control group). Sample size will be calculated and applied using the sample size calculation formula

Settings and conduct

Patients with advanced endometriosis undergoing surgery in the pediatric ward of Rasoul Akram Hospital. After surgery, the patients will be divided into three groups: treatment with dienogest and contraceptive pill (LD) and also a control group. Quality of life (WHOQOL-BREF), VAS, and three-point score questionnaires will be used before and in two stages of post-test and follow-up, 3 and 6 months after surgery, respectively, and then will compare between the three groups.

Participants/Inclusion and exclusion criteria

Initial diagnosis of endometriosis and chronic pelvic pain associated with endometriosis in surgery patients, informed consent to study, no pelvic pain originating from other organs

Intervention groups

This study was performed before and after the surgical procedure in three groups of patients with advanced endometriosis who received dienogest (2 mg) and contraceptive pills (LD) and also a placebo for the control group after surgery and compared.

Main outcome variables

Pain and quality of life in advanced endometriosis in surgery patients

General information

Reason for update

Add a control group to study and conduct experiments with three groups Correction of the realized time of the beginning and end of the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20191011045063N1**
Registration date: **2020-02-20, 1398/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-25, 1400/12/06**
Update count: **4**

Registration date

2020-02-20, 1398/12/01

Registrant information

Name
Gelareh Niakan
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8807 1886
Email address
g.niakan59@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

2018-03-27, 1397/01/07

Actual recruitment end date

2020-03-05, 1398/12/15

Trial completion date

2020-03-29, 1399/01/10

Scientific title

The comparison of treatment with dienogest and contraceptive oral pills on the improvement of pain, and quality of life in surgery patients with advanced endometriosis

Public title

The comparison of treatment with dienogest and contraceptive oral pills on the improvement of pain, and quality of life in surgery patients with advanced endometriosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Early diagnosis of endometriosis and chronic pelvic pain associated with endometriosis Patients with advanced endometriosis who underwent surgery Age 18 - 45 years Body mass index (BMI) 18.5 – 29.9 kg/m2; No gynecological malignancy No contraindications to OCP or dienogest No plans of pregnancy in the near No underlying diseases

Exclusion criteria:

Personal dissatisfaction for inclusion in the study Patients whose pelvic pain originates from other organs Use of gonadotropins or other hormones three months before surgery

Age

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

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **108**

Actual sample size reached: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a simple random method to assign participants to three groups. Eligible individuals will be randomly divided into three groups using Excel software and RANDBETWEEN command.

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 Iran University of Medical Sciences

Street address

shahrake gharb

City

Tehran

Province

Tehran

Postal code

1467864184

Approval date

2018-05-05, 1397/02/15

Ethics committee reference number

IR.IUMS.FMD..REC.1398.128

Health conditions studied

1

Description of health condition studied

Advanced endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Pain

Timepoint

Before surgery, 3 and 6 months after surgery

Method of measurement

Pelvic pain and dyspareunia scores are evaluated using the Visual Analogue Scale (VAS) and dysuria and dyschezia using a three-point score questionnire by possible answers to the items were “yes”, “no”, and “a little”.

Secondary outcomes

1

Description

Quality of life

Timepoint

Before surgery, 3 and 6 months after surgery

Method of measurement

Quality of life was measured using WHOQOL-BREF

2

Description

Edverse effects of the treatment

Timepoint

3 and 6 months after surgery

Method of measurement

Questionnaire

3

Description

Pain recurrence

Timepoint

6 months after surgery

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: The first group will receive the dienogest drug. Dosage of one tablet of 2 mg daily for six months

Category

Treatment - Drugs

2

Description

Intervention group: The second group will receive contraceptive pills. One tablet daily for six months

Category

Treatment - Drugs

3

Description

Control group: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Gelareh Niakan

Street address

No. 7, Falamak shomali Ave.,shahrake gharb

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Gelareh Niakan

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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

Iran University of Medical Sciences

Proportion provided by this source

10

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Gelareh Niakan

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abolfazl Mehdizadeh

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Gelareh Niakan

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

Not applicable

Data Dictionary

Not applicable