Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Comparative study on the effects of continuous administration of dienogest and continuous oral contraceptive pills on the recurrence of endometriosis symptoms after laparoscopic surgery

Protocol summary

Study aim

Compare the effects of dinogest and oral contraceptives in reducing the recurrence of endometriosis after endometriosis laparoscopy using questionnaires before surgery and after using the drugs (after surgery)

Design

This study is a two_side_blind randomized clinical trial. The way of sampling is convenience. In this study the patients have undergone laparoscopy for endometriosis are divided into 2 groups accidentally, there are 40 people in each group. One group will receive dinogest and the second group will receive oral contraceptives for 6 months.

Settings and conduct

All interventions are done in Beheshty and Alzahra hospitals. In this study two sided blindness is performed and the evaluator (person who asks and exams the clients after using the drug) does not know which drug is used and the analyser is unaware of the two groups under medication. The data is given to the analyser as separated codes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with 20 to 40 years of age; the tendency in the cooperation with the intervention; with symptoms of endometriosis ; patients referred to Isfahan's Alzahra and Shahid Beheshty hospitals.
Exclusion criteria: Patients whose addresses are changed and they are not available; patients with hormonal therapy three months prior to surgery; having contraindication for oral contraceptives.

Intervention groups

The participants are divided accidentally into two groups. One group will receive dinogest and the other group will receive oral contraceptives continuously after surgery.

Main outcome variables

Recurrence; pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120201008897N7**
Registration date: **2019-05-02, 1398/02/12**
Registration timing: **prospective**

Last update: **2019-05-02, 1398/02/12**
Update count: **0**

Registration date

2019-05-02, 1398/02/12

Registrant information

Name
Safoura Rouholamin
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-15, 1398/03/25

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative study on the effects of continuous administration of dienogest and continuous oral contraceptive pills on the recurrence of endometriosis symptoms after laparoscopic surgery

Public title
Effects of dienogest and oral contraceptive pills on endometriosis symptoms after laparoscopic surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diagnosis endometriosis via laparoscopy Premenopausal patients Patients who have symptoms of endometriosis before surgery (eg: dysmenorrhea, dyspareunia, chronic pelvic pain) Patients who have been referred to Isfahan's Alzhra and Shahid Beheshty hospitals Patients who do not have any decision for pregnancy during this study Patients with 20-40 years of age

Exclusion criteria:
Any hormonal therapy 3 months before surgery Having contraindications for using oral contraceptives Changing in the address so there is no access to the patient and her information History of surgery for treatment of endometriosis History of sexual dysfunction in patient or the partner Clients who undergo hysterectomy or ouophurectomy during surgery History of malignancy or heart disease

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization is block type, with blocks of size four. Before assigning the patients to two treatment groups, a container containing the letters A and B is provided with the number of participants with equal beads. The letters indicate the type of the intervention. The beads are drawn out randomly, and this work is continued until the beads are finished. Participant's sequencing is made with the created groups on the sequencing site: http://sealedenvelope.com.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study the outcome assessor and data analyzer don't know which participant has received dinogest and which one has received oral contraceptives.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
empty

2

Registry name
Secondary trial Id
Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezarjerib Street

City
Isfahan

Province
Isfehan

Postal code
1417614411

Approval date
2019-03-12, 1397/12/21

Ethics committee reference number
IR.MUI.MED.REC.1397.335

Health conditions studied

1

Description of health condition studied
laparoscopy of endometriosis

ICD-10 code
N80.9

ICD-10 code description
Endometriosis, unspecified

Primary outcomes

1

Description
Recurrence of endometriosis

Timepoint

6 months

Method of measurement

visual analog scale, WHO quality of life brief (WHOQOL-BREF) , Female Sexual Function Index (FSFI)

2

Description

pain

Timepoint

6 months

Method of measurement

visual analog scale, WHO quality of life brief (WHOQOL-BREF), Female sexual function index (FSFI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: group receiving dinogest 2mg/day continuously after surgery for 6 months

Category

Prevention

2

Description

Intervention group 2 : group receiving oral contraceptive (low dose monophasic) every day continuously after surgery for 6 months

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Safoura Rouholamin

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Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Negah Tavakolifard

Street address

Hezarjerib St., Isfahan University of Medical Sciences

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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

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

Reihaneh Valian Broujeni

Position

Resident of Obstetrics and Gynecology

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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Safoura Rouholamin

Position

Laparoscopic Fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Position

Laparoscopic Fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

comparing the effects of dinogest and oral contraceptives in reducing the recurrence of endometriosis after laparoscopy

When the data will become available and for how long

The time of accessibility is a month after publishing the information

To whom data/document is available

The information is available for everyone

Under which criteria data/document could be used

The information is available for everyone and everyone is allowed to do any kind of analyses on them

From where data/document is obtainable

address: University of medical siences, Hezar jarib strees, Darvazeh Shiraz, Isfahan postal code:1417614411 phone:00983136202020 website://alzahra.mui.ac.ir Dr Safoura Rouholamin

What processes are involved for a request to access data/document

The demandant should send her/his name, occupation, field of studying and purpose in an email. The requested information will be sent in a week

Comments