

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effect of periodically versus continuously oral contraceptives pills consumption on pain and anatomical recurrence in patients with endometrioma after laparoscopic surgery

Protocol summary

Study aim

comparison of the effect of periodically versus continuously oral contraceptives consumption on pain and anatomical recurrence in patients with endometrioma after laparoscopic surgery

Design

This is a randomized, open-labeled, single-center clinical trial.

Settings and conduct

This clinical trial will be carried out on 154 women attended the Arash Women's Hospital. All women aged 18 to 35 years old undergoing laparoscopic excision of endometrioma will be included in the study. The patients will randomly be divided into two groups: in one group contraceptive pills will be administered for continuous consumption and in another parallel group contraceptive pills will be administered for consumption in a cyclic manner (starting from 5 days of menstruation and continuing for 28 days, then discontinuing and continuing in the next cycle). In both treatment groups, the treatment lasts for one year. Then patients will be evaluated by ultrasound in the 3rd, 6th and 12th months after starting treatment and the endometrioma anatomic recurrence and endometrial thickness will be checked and their pain will be measured by the VAS criteria.

Participants/Inclusion and exclusion criteria

women aged between 18 and 35 years old with a history of laparoscopic endometrioma excision and $AMH \geq 2.5$ will be included in the study if did not receive another therapeutics during last 6 months and do not have a contraindication for estrogen or progesterone use.

Intervention groups

group 1: intake of contraceptive pills continuously for one year. group 2: intake of contraceptive pills in a cyclic manner for one year.

Main outcome variables

pain, ultrasonographic features of endometrioma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140111016161N8**

Registration date: **2018-12-15, 1397/09/24**

Registration timing: **retrospective**

Last update: **2018-12-15, 1397/09/24**

Update count: **0**

Registration date

2018-12-15, 1397/09/24

Registrant information

Name

Reyhaneh Hosseini

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 7771 9922

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of periodically versus continuously oral contraceptives pills consumption on pain and anatomical recurrence in patients with endometrioma after laparoscopic surgery

Public title

Effect of periodically versus continuously OCP on Endometrioma recurrence

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Development of endometrioma Age range from 18 to 35 years Unwillingness to pregnancy Anti-Müllerian hormone (AMH) higher than 2.5 Laparoscopic excision of endometrioma

Exclusion criteria:

Receive other therapies during the last 6 months (except for non-steroidal anti-inflammatory drugs) Contraindication for estrogen and progesterone regular use Unwillingness to change in menstrual cycles Pelvic inflammatory diseases Varicose veins known malformations of the genitourinary system in previous surgeries known urological, orthopedics, gastrointestinal disorders, and psychological disorder.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **134**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use the block randomization method by using: www.sealedenvelope.com

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 Tehran University of Medical Science

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Qods Street, Keshavarz Boulevard

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Postal code

1417653761

Approval date

2016-10-03, 1395/07/12

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.716

Health conditions studied**1****Description of health condition studied**

آندومتریوز تخمدان

ICD-10 code

N80.1

ICD-10 code description

Endometriosis of ovary

Primary outcomes**1****Description**

pain

Timepoint

3, 6 and 12 months after treatment starting

Method of measurement

Visual Analogue Scale

2**Description**

Anatomical recurrence of ovary endometrium

Timepoint

3, 6 and 12 months after treatment starting

Method of measurement

sonography

Secondary outcomes**1****Description**

Drug Complications (Increased Endometrial Thickness)

Timepoint

3, 6, and 12 months after starting treatment

Method of measurement

Ultrasound

2**Description**

Drug Complications (Venous thrombosis)

Timepoint

3, 6, and 12 months after starting treatment

Method of measurement

Medical history and physical examination

Intervention groups**1****Description**

Intervention group: patients take contraceptive pills continuously for one year.

Category

Treatment - Drugs

2**Description**

Control group: patients take contraceptive pill in cyclic form for one year.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash women's hospital

Full name of responsible person

Dr Reyhaneh Hoseini

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr Reihane hoseini

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available