Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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>=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

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Iran (Islamic Republic of)

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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

Street address
Qods Street, Keshavarz Bulevard

City
Tehran

Province
Tehran

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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No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran
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Sponsors / Funding sources

1

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Name of organization / entity
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Full name of responsible person
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Web page address
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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
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Position
Assistant professor
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