

# 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)

##### Phone

+98 21 7771 9922

##### Email address

r-hosseini@tums.ac.ir

##### 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](http://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 Boulevard

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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

**Street address**

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****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Ali Sahraian

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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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## Person responsible for scientific inquiries

### Contact

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

Hanieh Alam Beigi

**Position**

gynecologist

**Latest degree**

Specialist

**Other areas of specialty/work**

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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