

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Evaluation of the recurrence of dysmenorrhea, chronic pelvic pain and sonographic symptoms of endometrioma after laparoscopic surgery in the OCP alone treated group compared with the OCP plus N-acetylcysteine group

#### Protocol summary

##### Study aim

Determination of the recurrence of dysmenorrhea, chronic pelvic pain and sonographic symptoms of endometrioma after laparoscopic surgery in the OCP alone treated group compared with the OCP plus N-acetylcysteine group

##### Design

Double-blind randomized clinical trial with parallel groups and 1: 1 ratio

##### Settings and conduct

This study will be conducted at Laparoscopic Center of Arash Hospital on women with endometrioma who are eligible for the study after receiving written consent. After completing the demographic questionnaire, the participants will be divided into two groups. The first group will receive N-acetylcysteine 600 mg, three times a day, in 3 days a week for three months with continuous OCP for 6 months. The second group will continuously receive OCP alone for 6 months without the N-acetylcysteine. Blood samples will be taken from participants for measurement of Anti-Mullerian Hormone (AMH) and CA-125 Level once before operation and AMH level be rechecked 6 Months after operation.

##### Participants/Inclusion and exclusion criteria

Single women with endometrioma (based on the results of ultrasound and laparoscopy) who do not plan to become pregnant after surgery will be enrolled in the study.

##### Intervention groups

Group 1: Treatment with continuous OCP for 6 months plus N-acetylcysteine effervescent tablets for 3 months.  
Group 2: Treatment with continuous OCP alone for 6 months

##### Main outcome variables

Recurrence of dysmenorrhea; pelvic pain and ultrasound symptoms of endometrioma

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110530006640N4**

Registration date: **2018-04-16, 1397/01/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-16, 1397/01/27**

Update count: **0**

##### Registration date

2018-04-16, 1397/01/27

##### Registrant information

##### Name

Zahra Asgari

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7788 8755

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asgariza@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-02-28, 1395/12/10

##### Expected recruitment end date

2018-04-21, 1397/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the recurrence of dysmenorrhea, chronic pelvic pain and sonographic symptoms of endometrioma after laparoscopic surgery in the OCP alone treated group compared with the OCP plus N-acetylcysteine group

**Public title**

Comparison of the effect of OCP alone and in combination with N-acetylcysteine on clinical and ultrasound signs of endometrioma

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

being single Not having a tendency to pregnancy  
Diagnosis of ovarian endometrioma by ultrasound and confirmation by laparoscopic surgery

**Exclusion criteria:**

Patients who are planning a pregnancy after laparoscopic surgery

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **112**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sample size is 112 , with 56 people in each group. Block randomization method was designed by the group's epidemiologist using Stata version 13 software. The size of blocks considered is 6.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The random allocation list for patients is solely available to the epidemiologist. To hide the random allocation process, 112 card sequences of treatments will be written accordingly, and then the cards will be placed inside sealed envelopes. On each 10-digit random code packet, the order is written and the framework is written that the patient identification number is relevant and the methodologist will simply be aware of the design of the code. When the physician announces the eligibility of a patient, the methodologist will provide the envelope. The person evaluating the outcomes is a third person who is unaware of the random allocation process and type of treatment. To analyze the data, a statistician who is separate from the study process and who is unaware of all the processes performed will be used.

**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 Sciences

**Street address**

Research and Technology Dept, Sixth Floor of Central University Building, Corner of Quds Street, Keshavarz Blvd, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2017-02-18, 1395/11/30

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1395.1724

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

Ovarian endometrioma

**ICD-10 code**

N80.1

**ICD-10 code description**

Endometriosis of ovary

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

Ultrasound recurrence of endometrioma

**Timepoint**

Once before surgery and once 3 months after surgery and once at the end of the study (6 months after surgery)

**Method of measurement**

Transvaginal ultrasonically assessment of the ovaries

**2****Description**

Dysmenorrhea recurrence

**Timepoint**

Once before surgery and once 3 months after surgery

and once at the end of the study (6 months after surgery)

**Method of measurement**

Visual Analog Scale (VAS)

**3****Description**

Pelvic Pain Recurrence

**Timepoint**

Once before surgery and once 3 months after surgery and once at the end of the study (6 months after surgery)

**Method of measurement**

Visual Analog Scale (VAS)

**Secondary outcomes**

empty

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

Group 1: The first group will receive N-acetylcysteine 600 mg, three times a day, in 3 days a week for three months with continuous OCP for 6 months.

**Category**

Treatment - Drugs

**2****Description**

Group 2: The second group will continuously receive OCP alone for 6 months without the N-acetylcysteine.

**Category**

Treatment - Drugs

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

Arash Women Hospital

**Full name of responsible person**

Dr.Zahra Asgari

**Street address**

Arash Women 's Hospital, Eastern 162th St, Baghdarnia st, Resalat Highway, Tehranpars, Tehran ,Iran.

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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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rmo@tums.ac.ir

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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 Zahra Asgari

**Position**

Associate 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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**Full name of responsible person**

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**Position**

associate professor

**Latest degree**

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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**

Arezoo Maleki Hajiagha

**Position**

MS , Employee of research development center

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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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