

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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-Müllerian 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

Email address

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.

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3283

Fax

Email

Dr.zahra.asgari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Mohammad Ali Sahraeian

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

Phone

+98 21 8163 3698

Fax

+98 21 8163 3611

Email

rmo@tums.ac.ir

Web page address

http://vcr.tums.ac.ir/

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

Street address

Eastern 162th St, Baghdarnia st, Resalat Highway,
Tehranpars, Tehran ,Iran.

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 8755

Fax

+98 21 7788 8751

Email

asgariza@sina.tums.ac.ir

Web page address

Person responsible for scientific 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

Street address

Eastern 162th St, Baghdarnia st, Resalat Highway,
Tehranpars, Tehran ,Iran.

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 8755

Fax

+98 21 7788 8751

Email

asgariza@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Arezo Maleki Hajiagha

Position

MS , Employee of research development center

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Eastern 162th St, Baghdarnia st, Resalat Highway,
Tehranpars, Tehran ,Iran.

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3283

Fax

Email

arezoomaleki.h@yahoo.com

Web page address

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