

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Assessment of the effect of N-acetylcysteine drug and oral contraceptive pills on chronic pelvic pain and sonographic endometrioma recurrence rate after laparoscopic surgery in patients with endometrioma

Protocol summary

Study aim

Assessment of the effect of N-acetylcysteine drug and oral contraceptive pill on chronic pelvic pain and sonographic endometrioma recurrence rate after laparoscopic surgery in patients with endometrioma

Design

Clinical trial with control group, with parallel groups, double-blind, randomized with a sample size of 112

Settings and conduct

This study was performed in the laparoscopy center of Arash Women's Hospital (affiliated to Tehran University of Medical Sciences) on eligible women who were consented to participate in the study. The outcome assessor and the statistician were unaware of the randomization and interventions performed in the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: candidate for laparoscopic surgery for endometrioma; Presence of at least one documented endometrioma in two ultrasound findings. Non-inclusion criteria: Usual contraindications to Estrogens and Progestins; Women's desire to get pregnant after surgery

Intervention groups

Intervention group: Take one 600 mg effervescent N-acetylcysteine tablet three times a day (three times a week) for 3 months plus one oral contraceptive pill continuously used for 6 months. Control group: Use only one oral contraceptive per day continuously for 6 months

Main outcome variables

Endometrioma recurrence; Pelvic pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090526001952N11**

Registration date: **2019-11-15, 1398/08/24**

Registration timing: **retrospective**

Last update: **2019-11-15, 1398/08/24**

Update count: **0**

Registration date

2019-11-15, 1398/08/24

Registrant information

Name

Ashraf Moini

Name of organization / entity

Tehran University of Medical sciences

Country

Iran (Islamic Republic of)

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+98 21 7788 3283

Email address

hosp_arash@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2017-05-01, 1396/02/11

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of N-acetylcysteine drug and oral contraceptive pills on chronic pelvic pain and

sonographic endometrioma recurrence rate after laparoscopic surgery in patients with endometrioma

Public title

Effect of N-acetylcysteine drug and oral contraceptive pill on chronic pelvic pain and endometrioma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for endometrioma laparoscopy surgery
Presence of at least one documented endometrioma in two ultrasound findings

Exclusion criteria:

Patient who desire to become pregnant after surgery
Usual contraindications to estrogens and progestins

Age

To 40 years old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 112

Randomization (investigator's opinion)

Randomized

Randomization description

The sample size was 112 participants (56 people in each group). The block randomization method was developed by epidemiologist collaborator using version 13 of Stata software. The number of blocks considered is 6. To conceal the random allocation process, 112 treatment cards were written in sequential order, then the cards were placed in sealed envelopes. On each envelope, a random code was written with no sequences that only the methodologist was aware of the code. When the physician announced a patient's eligibility, the methodologist provided the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person who evaluated the final outcomes was unaware of the random allocation process and the type of treatment performed. Data were analyzed by a statistical expert who was separated from the study process and unaware of all the processes performed.

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

Vice-Chancellor in Research, Tehran University of Medical Science, near Qods st, keshavarz blvd.

City

Tehran

Province

Tehran

Postal code

1417614418

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

endometrioma

ICD-10 code

N80.1

ICD-10 code description

Endometriosis of ovary

Primary outcomes

1

Description

recurrence of endometrioma

Timepoint

3 and 6 months after intervention

Method of measurement

sonography

2

Description

Chronic pelvic pain

Timepoint

Before surgery and 3 and 6 months after intervention

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive 6 months continuous OCP in addition to 3 months N Acetylcysteine (OSVEH, Iran) according to the following schedule: effervescent tablets of N acetylcysteine 600 mg three times A day, three consecutive days a week

Category

Treatment - Drugs

2

Description

control group: receive an oral contraceptive pill a day for 6 months continuously

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women's Hospital

Full name of responsible person

Ashraf Moini

Street address

Arash Hospital, Rashid Ave, Resalat Highway, Tehranpars, 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

Street address

Deputy of Research and Technology, Qods St, Keshavarz Blv, Tehran, Iran

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rmo@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 Science

Full name of responsible person

Rana Karimi

Position

gynecologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Position

gynecologist

Latest degree

Specialist

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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

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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