Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
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 112participants (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, 112treatment 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 and3 and 6 months after intervention
Method of measurement
Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive 6 months continuous OCPin 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

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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
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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 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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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