

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of aspirin and placebo on pelvic pain and the number and size of endometriosis lesions after surgery

Protocol summary

Study aim

Comparison of the effect of aspirin and placebo on pelvic pain and the number and size of endometriosis lesions after surgery

Design

This study is designed as a randomized, triple-blind clinical trial with parallel groups with a sample size of 61 individuals per group.

Settings and conduct

This study will be done on 122 women with endometriosis undergoing surgery. After random allocation, they will be treated with OCP and placebo or OCP and aspirin daily for 6 months. Pelvic pain, dysmenorrhea, mass size, and menstrual bleeding will be evaluated after 3 and 6 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with endometriosis undergoing surgery, 18-40 years old
Exclusion criteria: All people who have contraindications to taking OCPs and aspirin (platelet disorders, bleeding disorders, gastrointestinal bleeding, severe dehydration, liver failure), pregnancy, Willing to become pregnant, Malignancy

Intervention groups

Control group: Intervention group: OCP and placebo daily for 6 months
Intervention group: OCP and Aspirin 80 mg daily for 6 months

Main outcome variables

Pelvic pain, Dysmenorrhea, Dyspareunia, Menstrual bleeding, The size and the number of masses

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090526001952N10**

Registration date: **2019-04-23, 1398/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-23, 1398/02/03**

Update count: **0**

Registration date

2019-04-23, 1398/02/03

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

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of aspirin and placebo on pelvic pain and the number and size of endometriosis lesions after surgery

Public title

Effect of Aspirin On treatment of endometriosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with endometriosis undergoing surgery 18-40 years old

Exclusion criteria:

All people who have contraindications to taking OCPs and aspirin (platelet disorders, bleeding disorders, gastrointestinal bleeding, severe dehydration, liver failure) Malignancy Willing to become pregnant pregnancy

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 122 people, with 61 people in each group. Block randomization method was designed by epidemiologist using STATA version 13 software. The number of participants in each block is 4.

Blinding (investigator's opinion)

Triple blinded

Blinding description

At the present study, we will use a placebo that is completely similar to aspirin, so that the physician and the patient will not be aware of the type of the intervention. Also, the person evaluating the outcomes is a third person who is unaware of the random allocation process and type of treatment. A statistician who is unaware of the type of interventions in each group will analyse the data. So, participants, the person evaluating the outcome, the physician and the analyzer, are all blind.

Placebo

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

City

Tehran

Province

Tehran

Postal code

WWW.TUMS.AC.IR

Approval date

2018-07-25, 1397/05/03

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.259

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

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

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

Pelvic pain

Timepoint

Before,3 and 6 months after the surgery

Method of measurement

Visual analog scale

2**Description**

Dysmenorrhea

Timepoint

Before,3 and 6 months after the surgery

Method of measurement

Visual analog scale and Questionnaire

3**Description**

Dyspareunia

Timepoint

Before,3 and 6 months after the surgery

Method of measurement

Questionnaire

Secondary outcomes**1****Description**

Menstrual bleeding

Timepoint

Before , 3 and 6 months after surgery

Method of measurement

Questionnaire

2

Description

The size and the number of masses

Timepoint

Before , 3 and 6 months after surgery

Method of measurement

Sonography

Intervention groups

1

Description

Intervention group: OCP and Asprin 80 mg daily for 6 months

Category

Treatment - Drugs

2

Description

Control group: Intervention group: OCP and placebo daily for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women's Hospital

Full name of responsible person

Ashraf moini

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Eastern 162th St, Baghdarnia st, 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

Qods St, Keshavarz Blv, Tehran, Iran

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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

Ashraf Moini

Position

Professor

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