

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 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)

###### Phone

+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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1653915981

**Phone**

+98 21 7771 9922

**Email**

A\_moini@royaninstitute.org

**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

**City**

Tehran

**Province**

Tehran

**Postal code**

1653915981

**Phone**

+98 21 7771 9922

**Email**

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 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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**Other areas of specialty/work**

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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