

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of prednisolone on pelvic pain in women with deep endometriosis

Protocol summary

Study aim

Determining the effect of prednisolone on pelvic pain in women with deep endometriosis

Design

Clinical trial(pilot) with a control group, with parallel groups, Triple -blind, randomized, phase3on 60 patients. Block random allocation method will be done using the website: www.sealedenvelope.com.

Settings and conduct

Based on the block randomization list, they are randomly assigned to two groups of patients referring to Arash Hospital. Prednisolone tablets are discontinued under the supervision of a doctor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: vaginal/rectal ultrasound confirmation of deep endometriosis, candidate for drug treatment to reduce pelvic pain, at least one year has passed after endometriosis surgery, age 18 to 45 years, no desire to get pregnant in the last 3 months Exclusion criteria : include oligomenorrhea for three months or more, initial need for surgical treatment of endometriosis, use of hormonal agents during the study period, or abnormal findings in gynecological examination except endometriosis and endometrioma over 5 cm, and contraindications to glucocorticoid use.

Intervention groups

In the placebo group, one 2 mg Verogest tablet(AntiPharmed Company) daily starts from the 10th day of the first menstrual period along with 2 placebo tablets after the baseline visit for 12 weeks. control group :was prescribed 2 tablets of prednisolone (10 mg Iran hormon company) along with Verogest 2 mg in the same way as the first group.

Main outcome variables

Dysmenorrhea , dyspareunia and dyschezia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140111016161N10**

Registration date: **2023-06-21, 1402/03/31**

Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

Registration date

2023-06-21, 1402/03/31

Registrant information

Name

Reyhaneh Hosseini

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7771 9922

Email address

r-hosseini@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-13, 1402/04/22

Expected recruitment end date

2024-01-12, 1402/10/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of prednisolone on pelvic pain in women with deep endometriosis

Public title

Investigating the effect of prednisolone

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

confirm with trans vaginal / trans rectal ultra sonography candidate for medical therapy At least one year after surgical treatment 18 to 45 years no desire to get pregnant in the last 3 months

Exclusion criteria:

Oligomenorrhea for three months or more Primary need for endometriosis surgical treatment Use of other hormonal agents during the study period Abnormal findings in women's examination except endometriosis Endometrioma above 5 cm Contraindications for glucocorticoid use

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 60 people, with 30 people in each group. The unit of study is the individual. We will use the block randomization method by using: www.sealedenvelope.com. The number of blocks considered is 4.

Blinding (investigator's opinion)

Double blinded

Blinding description

The list of random allocation of patients is only at the disposal of the clinic nurse. In order to hide the random allocation process, the sequence of treatments will be written on 60 cards in order. Then the cards will be placed inside sealed envelopes. When the doctor qualifies the patient to enter Determined for the study, the nurse provides the doctor with the envelope related to the type of intervention. In order to check the outcome, a doctor who was unaware of the type of intervention is used. Also, for data analysis, a statistician who is separate from the study process and from all The procedures performed are used in an uninformed manner. The study is double-blind. The patient is also unaware.

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 Bulevar

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Tehran

Province

Tehran

Postal code

1417653761

Approval date

2023-05-23, 1402/03/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.115

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

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

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

Dyspareunia

Timepoint

Before and 3 months after treatment starting

Method of measurement

Visual analogous scale

2**Description**

Dysmenorrhea

Timepoint

Before and 3 months after treatment starting

Method of measurement

Visual analogous scale

3**Description**

Dyschezia

Timepoint

Before and 3 months after treatment starting

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group : Patients use 2 tablets of prednisolone 5 mg (Iran Hormone Company) and one tablet of Verogest 2 mg (Ati Pharmed Company) daily for up to 3 months continuously.

Category

Treatment - Drugs

2**Description**

Control group: Patients use 2 tablets of placebo and one tablet of Verogest 2 mg (Ati Pharmed Company) daily for up to 3 months continuously.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash women's hospital

Full name of responsible person

Dr. Reyhaneh Hoseini

Street address

No.162 Alley (Abdul Majid) , Shahid Baghdarnia Street (North Rashid),Shahid Bagheri Haghway ,Resalat Highway , Tehran , Iranh

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Tehran University of Medical Sciences

Full name of responsible person

Dr Younesian

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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

Reyhaneh Hosseini

Position

Associate professor

Latest degree

Medical doctor

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