

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the effectiveness of Dienogest with medroxyprogesterone acetate in the treatment of pelvic pain and recurrence after laparoscopic surgery in patients with endometriosis

#### Protocol summary

##### Study aim

Comparison of the effectiveness of Dienogest with medroxyprogesterone acetate in the treatment of pelvic pain and recurrence of endometriosis after laparoscopic surgery

##### Design

Study Design: Single blinded phase 3 randomized clinical trial with parallel groups Study groups: 130 eligible women with endometriosis who underwent laparoscopic surgery will be randomly divided into two groups via the block randomization method.

##### Settings and conduct

After obtaining written consent, a questionnaire containing the required information, blood test, and vaginal ultrasound will be performed for eligible individuals. Dysmenorrhea, dyspareunia, and pelvic pain will be measured with a visual analog scale (VAS). Participants will be randomly divided into two groups: dienogest and medroxyprogesterone acetate. Three months after the intervention, pain, and side effects in both groups will be measured via VAS and a questionnaire. Six months after the intervention, the outcome variables will be re-assessed. The researcher and statistician will be unaware of how the interventions are allocated.

##### Participants/Inclusion and exclusion criteria

In this study, women aged 18 to 45 years with a laparoscopically confirmed endometriosis will be included. In the case of pregnancy, lactation, amenorrhea, vaginal bleeding, progesterone contraindication, oophorectomy, or hysterectomy during the study and use of some drugs (is described in the relevant section) will be excluded from the study.

##### Intervention groups

Group 1: Dienogest tablets will be taken daily for 3 months and then cyclically for the next 3 months (every month from day 10 of the cycle for 2 weeks) Group 2:

Medroxyprogesterone acetate 10 mg twice daily for 3 months and then cyclically for the next 3 months (every month from day 10 of the cycle for 2 weeks)

##### Main outcome variables

Recurrence of endometriosis; Pelvic pain; Dysmenorrhea; Dyspareunia; side effects

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170917036227N5**

Registration date: **2020-12-16, 1399/09/26**

Registration timing: **prospective**

Last update: **2020-12-16, 1399/09/26**

Update count: **0**

##### Registration date

2020-12-16, 1399/09/26

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7771 9922

##### Email address

mvahid@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-21, 1399/10/01

##### Expected recruitment end date

2022-04-20, 1401/01/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of Dienogest with medroxyprogesterone acetate in the treatment of pelvic pain and recurrence after laparoscopic surgery in patients with endometriosis

**Public title**

Comparison of Dienogest with medroxyprogesterone acetate in the treatment of pelvic pain and recurrent endometriosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women aged 18-45 years old Endometriosis confirmation via laparoscopy and histopathologic assessment

**Exclusion criteria:**

Pregnancy or Breast Feeding Plan to become pregnant Amenorrhea (no more menstruation - equal to 3 months in the last 6 months) Undiagnosed genital bleeding Recent use of hormonal agents Contraindications to the use of progesterone Having a risk factor for decreased bone density Use of acitretin, anticoagulants such as warfarin, antidiabetic drugs, aperitif and, artemether, atazanavir, barbiturates, bexarotene, Boceprevir, bosentan, thrombogenic drugs, clobazam, anticonvulsant drugs (carphenazine, Topiramate, valproic acid, lamotrigine, phenytoin ...), Darunavir, Deferasirox, Efavirenz, Felbamate, Griseofulvin, Mifepristone, Nelfinavir, Neuruppin, Selegiline, Thalidomide, Tranexamic Acid and Voriconazole

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**

Target sample size: **130**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization method will be designed by an epidemiologist using STATA version 13 software. The size of blocks considered will be 4.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The randomization list will be solely available to the epidemiologist. To hide the random allocation process, 130 card sequences of treatments will be written

accordingly, and then the cards will be placed inside sealed envelopes. A 10-digit random code will be written on each packet as the patient's identification number. When the physician announces the eligibility of a patient, the nurse will provide the envelope and the type of treatment will be selected based on the type mentioned in the envelope. Data analysis will be performed by a statistician who is unaware of all 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 Sciences

**Street address**

Floor 6; Vice Chancellor of Research and Technology; Qods street; Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2020-12-01, 1399/09/11

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1399.825

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

Endometriosis

**ICD-10 code**

N80

**ICD-10 code description**

Endometriosis

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

Recurrence of endometriosis

**Timepoint**

Six months after the start of the intervention

**Method of measurement**

Transvaginal ultrasound

## 2

### **Description**

Pelvic pain

### **Timepoint**

Three and six months after the start of the intervention

### **Method of measurement**

Visual Analog Scale (VAS)

## 3

### **Description**

Dysmenorrhea

### **Timepoint**

Three and six months after the start of the intervention

### **Method of measurement**

Visual Analog Scale (VAS)

## 4

### **Description**

Dyspareunia

### **Timepoint**

Three and six months after the start of the intervention

### **Method of measurement**

Visual Analog Scale (VAS)

## 5

### **Description**

Side effects

### **Timepoint**

Three and six months after the start of the intervention

### **Method of measurement**

check list

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Dienogest tablets will be taken daily for 3 months and then cyclically for the next 3 months (every month from day 10 of the cycle for 2 weeks)

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 2: Medroxyprogesterone acetate 10 mg twice daily for 3 months and then cyclically for the next 3 months (every month from day 10 of the cycle for 2 weeks)

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Arash Women's Hospital

##### **Full name of responsible person**

Dr. Reihaneh Hossein

##### **Street address**

Rashid street; Tehranpars; Resalat highway

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1653915981

##### **Phone**

+98 21 7771 9922

##### **Email**

hosparash@tums.ac.ir

## **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**

Floor 6; Vice Chancellor of Research and Technology;  
Qods street; Keshavarz Blvd

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##### **Province**

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##### **Postal code**

1417653761

##### **Phone**

+98 21 8163 3619

##### **Fax**

+98 21 8163 3611

##### **Email**

rmo@tums.ac.ir

##### **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

+98 21 7771 9922

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+98 21 7788 3196

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mvahid@sina.tums.ac.ir

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Haniyeh Roodi

**Position**

Gynecology Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Arash women's hospital, Rashid Ave, Tehranpars,  
Reslat highway

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**Province**

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**Postal code**

1653915981

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**Email**

behroozmoogooie@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Haniyeh Roodi

**Position**

Gynecology Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Marzieh Vahid Dastjerdi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Arash women's hospital, Rashid Ave, Tehranpars,  
Reslat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1653915981

**Phone**

**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