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 assessmnet
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
City
Tehran
Province
Tehran
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

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

City

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Province

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Postal code

1653915981

Phone

+98 21 7771 9922

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+98 21 7788 3196

Email

behroozmoogooie@yahoo.com

Web page address

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

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

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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

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Email

behroozmoogooie@yahoo.com

Web page address

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