Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Investigating the effect of Dienogest with and without pelvic floor physiotherapy on the pain level of endometriosis sufferers.

Protocol summary

Study aim
Providing a method for possible better exposure to pain in endometriosis patients

Design
A clinical trial with a control group. Randomized by drawing a card. Phase 2 on 100 patients.

Settings and conduct
This study is a randomized clinical trial. The participants are selected from the outpatient endometriosis clinic of Taleghani Hospital in 1403 and all of them sign an informed consent period. The participants are randomly divided into two groups (Dinogest treatment along with pelvic physiotherapy) and the control group (Dinogest treatment and Maneuver Sham) are placed. And in both cases, the pain caused by dysmenorrhea, dyschezia, and dyspareunia will be evaluated using the Visual Analogue Scale method. And the questionnaire is filled based on it. Pelvic floor physiotherapy will be performed for 12 fifty-minute sessions, repeated three times a week. These women were instructed not to stop endometriosis medication during the study. Randomization is done and after three months, the pain score is evaluated based on their VAS and filled in the questionnaire and compared with the previous three months.

Participants/Inclusion and exclusion criteria
Include criteria:Women aged 20-45 with endometriosis All of them have been using dinogest for at least 3 months. reported symptoms of pelvic pain (CPP or dyspareunia and dysmenorrhea). Exclude criteria: Pregnancy, pace maker, , epilepsy, cardiac arrhythmia, cancer, acute pelvic inflammatory disease, difficulty understanding instructions.

Intervention groups
Participants will be randomly assigned to two groups (dienogest treatment plus pelvic physiotherapy) and a control group (dienogest treatment and sham maneuver). In both groups, pain due to dysmenorrhea, dyspareunia, and dyspareunia will be assessed using the Visual Analogue Scale.

Main outcome variables
Intensity of pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241107063631N1**
Registration date: **2024-12-03, 1403/09/13**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-03, 1403/09/13**
Update count: **0**

Registration date
2024-12-03, 1403/09/13

Registrant information
Name
maral hosseinzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8807 9143
Email address
maral.hosseinzadeh65@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-11-17, 1403/08/27
Expected recruitment end date
2025-02-18, 1403/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Dienogest with and without pelvic floor physiotherapy on the pain level of endometriosis sufferers.

Public title
The effect of pelvic physiotherapy in reducing pain in patients with endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women aged 20-45 with endometriosis. All of them have been using dinogest for at least 3 months All of them reported symptoms of pelvic pain (CPP or dyspareunia and dysmenorrhea).

Exclusion criteria:
pregnancy Pace maker Reduced skin sensitivity, , acute , cognitive impairment, and Epilepsy, Cardiac arrhythmia Cancer Acute pelvic inflammatory disease Gel or electrode sensitivity, difficulty understanding instructions

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random Sequence Generation will be done by simple randomization and by shuffling the cards. A number of cards will be prepared as the first group and the same number of cards for the next groups. Then, by shuffling them, one card will be removed and its assignment will be recorded, and that card will be returned to the other cards. Then, the cards will be shuffled again and another card will be removed. This process will continue until a random sequence is reached according to the sample size.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of shahid beheshti University of Medical Sciences

Street address
taleghani hospital . Arabi street . daneshjoo street

City
tehran

Province
Tehran

Postal code
1115119857

Approval date
2024-11-10, 1403/08/20

Ethics committee reference number
IR.SBMU.RETECH.REC.1403.430

Health conditions studied

1

Description of health condition studied
Endometriosis

ICD-10 code
N80.3

ICD-10 code description
Endometriosis of pelvic peritoneum

Primary outcomes

1

Description
Pain score in the questionnaire

Timepoint
Before the start of the intervention - one month after the start of physiotherapy

Method of measurement
mode Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dienogest treatment with pelvic physiotherapy - Pelvic floor physiotherapy will be performed for 12 sessions of fifty minutes, repeated three times a week. It includes thirty minutes of visceral manipulation (internal vaginal and external (abdomen) and twenty minutes of pelvic floor muscle exercises. The patient is placed in a supine position with bent knees. Pelvic floor exercises are divided into four phases. The proprioceptive phase in the first week includes

proprioceptive exercises for adequate understanding of the exercises and performing fast and slow contractions. The simple phase is performed in the second week with the aim of improving the control of fast and slow contractions during simple functional activities. The advanced phase is performed in the third week in which functional exercises with a greater amplitude are performed. The strength phase is performed in the last week to increase the strength of contraction. In all sessions, contractions will be performed for slow and fast fibers.

Category

Treatment - Other

2

Description

Control group: Dienogest treatment and sham maneuver (a dummy intervention is used as an intervention in the control group, and the practical methods are applied in a fake manner in the control group). Dienogest was also prescribed from Ati Pharmed Pharmaceutical Company at a dose of 2 mg daily.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

taleghani hospital

Full name of responsible person

Saghar Salehpour

Street address

taleghani hospital-arabi street-yaman street-chamran highway -Tehran

City

tehran

Province

Tehran

Postal code

3816149369

Phone

+98 21 2303 1307

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info@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin zarghi

Street address

Valenjak - Student Square - Arab Street - Taleghani Hospital

City

Tehran

Province

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1985711151

Phone

+98 21 2243 2560

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taleghanihospital@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maral Hosseinzadeh

Position

fellowship Assistant

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No:33,darya staion , farahzadi blvd, Qods Town

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146974541

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maral.hosseinzadeh65@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maral Hosseinzadeh

Position

fellowship Assistant

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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