

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

the effect of dopamine agonists (cabergoline) on reducing pain in endometriosis patients

Protocol summary

Study aim

effect of dopamine agonists (cabergoline) on pain reduction in endometriosis patients.

Design

A clinical trial with control and parallel groups, randomized, phase 3 on 72 patients. The permutation blocks method produced the sequence of randomly allocated people to the studied groups. A random allocation sequence of people was done using Random Allocation Software and a block size of four.

Settings and conduct

patients with endometriosis who refer to the gynecology clinic of Ghaem and Imam Reza (AS) hospitals are included in the study based on inclusion and exclusion criteria. Before starting treatment, on the first day of menstruation, the severity of dysmenorrhea pain in patients is measured using the VAS standard.

Participants/Inclusion and exclusion criteria

inclusion criteria: Diagnosis of clinical endometriosis by observing pain and tenderness in the pelvic examination along with endometriosis nodules in the vaginal examination, firm and motionless uterus and confirmed by ultrasound or MRI (observation of endometriosis cysts and nodules) Diagnosis of grade I-IV endometriosis based on r-ASRM criteria during diagnostic laparoscopy during the previous 12 months Dysmenorrhea complaints with EAPP score >30 or >40, normal pap smear. Exclusion criteria: endometriosis who were treated with GnRH agonist less than 6 months ago, or danazol or progesterone pills less than 3 months ago, or birth control pills less than 1 month ago.

Intervention groups

Patients with endometriosis will be given dopamine agonists (cabergoline) 0.5 twice a week for three months and in Control groups will be given the dingiest 2 milligrams once a day for three months.

Main outcome variables

EAPP on the first day of menstruation and at the end of the first, second, and third month is treatment.

General information

Reason for update

In practice, changes were made to the exclusion criteria, and the study was conducted double-blind.

Acronym

IRCT registration information

IRCT registration number: **IRCT20181030041503N6**

Registration date: **2022-12-20, 1401/09/29**

Registration timing: **prospective**

Last update: **2024-12-15, 1403/09/25**

Update count: **1**

Registration date

2022-12-20, 1401/09/29

Registrant information

Name

Malihe Mahmoudinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9878

Email address

mahmoudiniam@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

2022-12-22, 1401/10/01

Actual recruitment end date

2023-12-22, 1402/10/01

Trial completion date

empty

Scientific title

the effect of dopamine agonists (cabergoline) on reducing pain in endometriosis patients

Public title

the effect cabergoline on reducing pain in endometriosis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of clinical endometriosis by observing pain and tenderness in the pelvic examination along with endometriosis nodules in the vaginal examination, firm and motionless uterus and confirmed by ultrasound or MRI (observation of endometriosis cysts and nodules) Diagnosis of grade I-IV endometriosis based on r-ASRM criteria during diagnostic laparoscopy during the previous 12 months Dysmenorrhea complaint with EAPP score >30 or >40 Normal pap smear

Exclusion criteria:

Endometriosis treated less than 6 months ago with a GNRH agonist or less than 3 months ago danazol or progesterone tablets or less than 1 month ago with oral contraceptives. Severe pain unrelieved by Cabergoline necessitating the use of other analgesics lack of willingness to continue in the study non-adherence to the treatment regimen any adverse reactions to the medication (particularly allergies) Sensitivity to the medication and incorrect medication intake in the control group

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the permutation blocks method was used to generate the sequence of random assignments of people to the studied groups. A random allocation sequence of people was done using Random Allocation Software and a block size of four. The permutation block method is one of the random allocation methods in which each block is selected as an integer multiple of the number of studied groups. In this study, there are four blocks: AABB, ABAB, BBAA, and BABA. One of the blocks is randomly selected. If the first block, AABB, is selected, the first and second person will be assigned to group A, and the third and fourth person will be assigned to group B. And this process continues until all samples are allocated. The feature of this method is that the two study groups will have equal numbers. Random Allocation Software is free

software for creating a random sequence using scientific methods including the permutation block method for allocating subjects to treatment groups, which was developed by Dr. Mahmoud Saghaei (<https://www.saghaei.net>).

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is unaware of the treatment, patients are coded A and B based on random assignment, and the researcher gives the drug to the patient based on patient code A or B. The statistical consultant who analyzes the

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mashhad university of medical sciences Ethics committee

Street address

Vice chancellor of Research, Mashhad university of Medical Sciences, Mashhad University of Medical Sciences ,University Avenue.Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-07-02, 1401/04/11

Ethics committee reference number

IR.MUMS.REC.1401.158

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

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

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

Severe dysmenorrhea pain

Timepoint

On the first day of menstruation and at the end of the first, second and third month of treatment

Method of measurement

By 10-point visual analogue scale (VAS)

Secondary outcomes

empty

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

Intervention group: Patients with endometriosis who will be given dopamine agonists (cabergoline) 0.5 milligrams twice a week for three months.

Category

Treatment - Drugs

2**Description**

Control group: Patients with endometriosis who will be given dinoprost 2 milligrams once a day for three months.

Category

Treatment - Drugs

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

Imam Reza hospital

Full name of responsible person

Elahe Khaleghzadeh

Street address

Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

presidentoffice@mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

malihe mahmoudinia

Street address

Imam Reza Hospital, Imam Reza St., Mashhad, Iran

City

mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3853 4021

Email

mahmoudiniam@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Elahe Khaleghzadeh

Position

Specialized assistant for women

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Bahonar

City

Mashhad

Province

Razavi Khorasan

Postal code

9178143179

Phone

+98 51 3614 4942

Email

elahekhaleghzadeh@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Mahmoudinia

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 7, Saremi 24/1 Ave., Hashemieh Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9135913556

Phone

+98 51 3882 9878

Fax

Email

mahmoudiniam@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Mahmoudinia

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 7, Saremi 24/1 Ave., Hashemieh Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9135913556

Phone

+98 51 3882 9878

Fax

Email

mahmoudiniam@mums.ac.ir

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