Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the impact of Cabergolin and a placebo on pelvic pain after laparoscopic surgery in cases of endometriosis

Protocol summary

Study aim
Comparative study of the impact of Cabergoline and a placebo on pelvic pain after laparoscopic surgery in cases of endometriosis

Design
This is a randomized triple-blind phase 3 clinical trial involving a total of 200 patients; 100 patients in the case group allocated to 100 patients in the control group. For randomization, 100 "A" labels and 100 "B" labels covered in envelopes are placed in a box. For each patient an evelope is drawn out of the box. The physician responsible for evaluating the outcomes, the patients, and the data analyst are be blinded to groups assignments.

Settings and conduct
This randomized, clinical trial with a case group (Dienogest plus Dostinex) and a control group (Dienogest plus placebo) will be conducted at the IVF clinic of Yas Hospital of Tehran. Random allocation will be used regarding case and control groups. The patients, physicians evaluating the outcomes, and data analysts will be blinded to the group assignments.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirmed endometriosis by pathology in addition to good quality embryos Exclusion criteria: Hypersensitivity to cabergoline, BMI > 30, diabetes mellitus, hydrosalpinx, severe male factor, AMH < 1 Women aged 20-40 with endometriosis and pelvic pain undergone laparoscopy

Intervention groups
Intervention group: Following laparoscopy for endometriosis, participants are prescribed a weekly dose of 0.5 mg Cabergoline along with daily Dinogest for 3 months, after which pregnancy outcomes will be evaluated. Control group: Following laparoscopy for endometriosis, participants are prescribed a weekly dose of placebo along with daily Dinogest for 3 months, after which pregnancy outcomes will be evaluated

Main outcome variables
Pelvic pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091012002576N39**
Registration date: **2024-03-29, 1403/01/10**
Registration timing: **prospective**

Last update: **2024-03-29, 1403/01/10**
Update count: **0**

Registration date
2024-03-29, 1403/01/10

Registrant information

Name
Fatemeh Davari Tanha

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 8831 3955

Email address
fdavaritanha@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-03, 1403/01/15

Expected recruitment end date
2025-04-04, 1404/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the impact of Cabergolin and a placebo on pelvic pain after laparoscopic surgery in cases of endometriosis

Public title
The effect of Cabergolin on pelvic pain in endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Approved endometriosis by pathology Presence good quality embryo

Exclusion criteria:
Hypersensitivity to cbergoline BMI>30 Diabetes melitus Hydrosalpinx Severe male factor AMH<1

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

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation rule: At first, on special unmarked papers, 100 A letters and 100 B letters are written. Then all(200) are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly without replacement. Based on the letter written on it, the intended intervention is performed on the patient. In addition, interventions A (Dostinex) or B (placebo group) are determined by lottery.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients and care provider (who will done randomization) are blinded regarding the groups (by using blacebo of Dostinex the same form, taste),and analyzer only sees the codes in data sheet and is blinded regarding the groups .

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Tehran University of medical sciences

Street address
Sixth floor of central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd

City
Tehran

Province
Tehran

Postal code
1597856511

Approval date
2024-03-04, 1402/12/14

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.715

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
Pelvic pain

Timepoint
Before and three months after surgery

Method of measurement
VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After laparoscopy for endometriosis, Cabergolin 0.5 mg/week, Aboreihan Company plus dinogest 2.5 mg /daily for 3 months will be prescribed then pelvic pain evaluated.

Category
Treatment - Drugs

2

Description
Control group: After laparoscopy for endometriosis, placebo (placebo Cabergolin 0.5 mg/week, Aboreihan Company) plus dinogest 2.5 mg /daily for 3 months will be prescribed then pelvic pain evaluated.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yas hospital
Full name of responsible person
Fatemeh Davari Tanha
Street address
Yas hospital, North Nejatollahi Avenue, Villa Street
City
Tehran
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1598718311
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Fatedavtanha@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Akbari Sari
Street address
Sixth floor of central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd
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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
Fatemeh Davari Tanha
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
SPSS data for main outcome

When the data will become available and for how long
After completing project

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
The data is only available to the project manager, Dr. Davari, and any analysis must be done with her opinion.

From where data/document is obtainable
Dr. Davari through email (fdavaritanha@sina.tums.ac.ir)

What processes are involved for a request to access data/document
Any request must be made in writing and accompanied by a proposal with an ethics code under the supervision of Dr. Davari.

Comments