

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison the impact of Cabergolin and a placebo on IVF outcomes after laparoscopic surgery in cases of endometriosis

Protocol summary

Study aim

Comparative study of the impact of Cabergoline and a placebo on IVF outcomes 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 envelope 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, triple-blinded 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. 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

Women aged 20-40 with infertility undergone laparoscopy 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

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

Main outcome variables

Chemical and clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002576N35**

Registration date: **2024-01-17, 1402/10/27**

Registration timing: **prospective**

Last update: **2024-01-17, 1402/10/27**

Update count: **0**

Registration date

2024-01-17, 1402/10/27

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-20, 1402/10/30

Expected recruitment end date

2026-01-20, 1404/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the impact of Cabergolin and a placebo on IVF outcomes after laparoscopic surgery in cases of endometriosis

Public title

Cabergolin effect on IVF for 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 **20 years** old to **40 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 ,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

Deputy of Research of Tehran University of medical sciences, sixth floor, Central building, Ghods Avenue, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

159781597815

Approval date

2023-12-22, 1402/10/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.460

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

Infertility

ICD-10 code

N97.8

ICD-10 code description

Female infertility of other origin

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

Chemical pregnancy

Timepoint

Two weeks after embryo transfer

Method of measurement

Blood sample for BhCG

Secondary outcomes**1****Description**

Clinical pregnancy

Timepoint

Four weeks after embryo transfer

Method of measurement

Heart beat activity in transvaginal sonogram

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

Control group: After laparoscopy for endometriosis, placebo (placebo Cabergolin 0.5mg/week, Aboreihan Company) plus dinogest 2.5 mg/daily for 3 months will be prescribed then pregnancy outcome evaluated.

Category

Treatment - Drugs

2

Description

Intervention group: After laparoscopy for endometriosis, Cabergolin 0.5 mg, weekly plus dinogest daily for 3 months will be prescribed then pregnancy outcome 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, Karim khan
Zand Bridge, Villa Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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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

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Data of main outcome

When the data will become available and for how long

After publishing article

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific research

From where data/document is obtainable

Fateme Davari Tanha

What processes are involved for a request to access data/document

Requesting by mail

Comments