Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison between Dienogest and GnRH agonist on pregnancy outcome of infertile endometriosis women after laparoscopy

Protocol summary

Study aim
Comparison between Dienogest and GnRH agonist on pregnancy outcome after laparoscopic surgery in endometriosis.

Design
This is a randomized double-blind ,placebo control, phase 3 clinical trial involving a total of 200 patients; 100patients in the case group allocated to 30 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, the patients, and the data analyst are be blinded to groups assignments.

Settings and conduct
This randomized, double-blinded ,clinical trial with a case group (dinogest) control group (Gnrh_a) will be conducted at the IVF clinic of Yas Hospital. Random allocation will be used regarding case and control groups. The investigator, and data analysts will be blinded to the group assignments.

Participants/Inclusion and exclusion criteria
Inclusion criteria : Endometriosis; deep infilterating endometriosis; Infertility Exclusion criteria: Hypersensitivity to dinogest or Gnrh_agonist

Intervention groups
Intervention group:After laparoscopic Surgery for Sever Endometriosis and DIE 100 patients will use Tablet Dinogest for three months.

Main outcome variables
Take home baby

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091012002576N40**
Registration date: **2024-04-02, 1403/01/14**
Registration timing: **prospective**
Last update: **2024-04-02, 1403/01/14**
Update count: **0**

Registration date
2024-04-02, 1403/01/14

Registrant information

Name
Fatemeh Davari Tanha

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 8831 3955

Email address
fdavaritanha@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-19, 1403/01/31

Expected recruitment end date
2025-04-20, 1404/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between Dienogest and GnRH agonist on pregnancy outcome of infertile endometriosis women after laparoscopy

Public title
Dinogest effect on pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Deep infilterating endometriosis Infertility
Exclusion criteria:
Hypersensitivity to dinogest or Gnrh_agonist

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
In Random allocation rule: First 100 letters A and 100 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A (case group) or B (control group) are determined by a lot.

Blinding (investigator's opinion)
Double blinded

Blinding description
Physician who evaluate outcome is blinded regarding the groups ,and analyzer only sees the codes in data sheet .

Placebo
Not 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
1597815978

Approval date
2024-02-20, 1402/12/01

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.680

Health conditions studied

1

Description of health condition studied
Infertility due to endometriosis

ICD-10 code
N97.8

ICD-10 code description
Female infertility of other origin

Primary outcomes

1

Description
Ongoing pregnancy

Timepoint
After 20 weeks of pregnancy

Method of measurement
History taking

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After laparoscopic surgery for Deep infilterating endometriosis tablet Dienogest 2mg/day for three months willbe used.

Category
Treatment - Drugs

2

Description
Control group: After laparoscopic surgery for Deep infilterating endometriosis GNRH AGONIST 11.25 will be used for three months .

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

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Tehran
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1597815978
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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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Herc.tums@gmail.com
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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Email

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

SPSS FILE

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

Related scientific analysis

From where data/document is obtainable

Email to Fatedavtanha@gmail.com

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

Formal request

Comments