Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Dienogest and GnRH agonist on pelvic pain & pregnancy outcome after laparoscopic surgery in endometriosis

Protocol summary

Study aim
Evaluation of the effect of Dienogest and GnRH agonist on pelvic pain after laparoscopic surgery in endometriosis

Design
A randomized clinical trial on 104 patients with Deep infilterating endometriosis after laparoscopic surgery will be conducted in case group (table Dienogest 2mg/d for 3months) or control group(Gnrh_agonist for 3 months), then pelvic pain & fertility outcome will be evaluated.

Settings and conduct
A randomized clinical trial will be conducted on patients with history of laparoscopy for DIE and medical treatment with dinogest or Gnrh_agonist at Yas hospital

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

Intervention groups
After laparoscopic Surgery for Sever Endometriosis and DIE 52 patients will use Tablet Dinogest for three months

Main outcome variables
Dysmenorrhoea; dysparunia ،Dyschezia; fertility outcome

General information

Reason for update
The pelvic painand fertility outcome will be reported for fifty52 patients in each group.

Acronym

IRCT registration information
IRCT registration number: **IRCT20091012002576N25**
Registration date: **2022-03-02, 1400/12/11**
Registration timing: **prospective**

Last update: **2024-05-23, 1403/03/03**
Update count: **2**

Registration date
2022-03-02, 1400/12/11

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
2022-03-06, 1400/12/15

Expected recruitment end date
2022-09-06, 1401/06/15

Actual recruitment start date
2022-04-04, 1401/01/15

Actual recruitment end date
2022-10-12, 1401/07/20

Trial completion date
2023-03-11, 1401/12/20

Scientific title
Evaluation of the effect of Dienogest and GnRH agonist on pelvic pain & pregnancy outcome after laparoscopic surgery in endometriosis

Public title
The effect of Dienogest and GnRH agonist on pelvic pain & pregnancy outcome after laparoscopic surgery in endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Endometriosis deep infilterating endometriosis Infertility

Exclusion criteria:

Hypersensitivity to dinogest or Gnrh_agonist

Age

From **20 years** old to **42 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **104**

Actual sample size reached: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

In Random allocation rule: First 52 letters A and 52 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)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Comittee of Tehran University of Medical Sciences

Street address

Yas hospital, North Nejatollahi avenue, Karim khan zand Bridge, Villa street

City

Tehran

Province

Tehran

Postal code

159781597878

Approval date

2021-11-28, 1400/09/07

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.964

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N97.8

ICD-10 code description

Female infertility of other origin

Primary outcomes

1

Description

Evaluation of dysmenorrhoea &dysparunia and Dyschezia

Timepoint

Thre months adter surgery

Method of measurement

Questionnaire for female sexual function index and Questionnaire for visual acuity scale

2

Description

Chemical pregnancy

Timepoint

Two weeks after embryo transfer

Method of measurement

Positive BhCG

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

Four weeks after embryo transfer

Method of measurement

Vaginal ultrasound

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

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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
Dr. 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)
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