Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of Simvastatin and gonadotropin-releasing hormone agonist to prevent recurrence of endometriosis

Protocol summary

Summary

This research has been conducted to detect the effect of Simvastatin on the treatment of endometriosis; inhibition of recurrence of endometriotic lesions, decreasing dyspareunia, pelvic pain and dysmenorrhea. Methods: The samples are the women that have laparoscopy and their histological result is endometriosis .Sixty patients will be divided in two groups (Simvastatin and GNRH agonist) in a randomized and double blind manner. In GNRH agonist group 4 doses of Decapeptyle will be injected and Simvastatin group will take one tablet of 20mg Simvastatin per day. Severity of dyspareunia, pelvic pain and dysmenorrhea will be evaluated by Visual Analogue Scale in the day after operation and one month after termination of medical treatment. The patients will have second laparoscopy for evaluation of severity of disease during one month after termination of medical treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009123384N5**
Registration date: **2010-12-25, 1389/10/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-12-25, 1389/10/04

Registrant information

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Name of organization / entity
Endocrine research center

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Recruitment status
Recruitment complete

Funding source
Iran University of Medical Sciences

Expected recruitment start date
2010-11-22, 1389/09/01

Expected recruitment end date
2011-11-22, 1390/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of Simvastatin and gonadotropin-releasing hormone agonist to prevent recurrence of endometriosis

Public title
Effect of Simvastatin on recurrence of endometriosis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Patients who have laparoscopy and their histological result is endometriosis. Exclusion criteria: Patients who don’t like to do laparoscopy or take drug.

Age
No age limit

Gender
Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Iran University of Medical Sciences

Street address

Hemat highway

City

Tehran

Postal code

Approval date

2010-06-13, 1389/03/23

Ethics committee reference number

1707575

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

C54.1

ICD-10 code description

Endometrium

Primary outcomes

1

Description

Recurrence of endometriosis

Timepoint

First & 6 months after treatment

Method of measurement

Laparoscopy

Secondary outcomes

1

Description

severity of dyspareunia

Timepoint

the day after operation and one month after termination of medical treatment

Method of measurement

Visual Analog Scale

2

Description

pelvic pain

Timepoint

the day after operation and one month after termination of medical treatment

Method of measurement

Visual Analog Scale

Intervention groups

1

Description

GNRH agonist group: 4 doses of Decapeptyle injection

Category

Treatment - Drugs

2

Description

Simvastatin group: one tablet of 20mg Simvastatin per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Maziar Moradi

Street address

Hemat highway

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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty