

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 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 Decapeptide 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

##### Name

Ameneh Ebrahim Valoojerdi

##### Name of organization / entity

Endocrine research center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8894 5247

##### Email address

info@lapsurg.ir

##### 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

**City**  
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

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences

**Full name of responsible person**  
Fariba Almasi

**Position**  
Associate Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Ameneh Ebrahim Valoojerdi

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**Other areas of specialty/work**

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**Phone**

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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*