

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Investigating the quality of life and chronic pelvic pain in 40-50-year-old women with endometriosis treated by hysterectomy and laparoscopic salpingo-ferectomy compared to conservative laparoscopic surgery.

#### Protocol summary

##### Study aim

Determining quality of life and chronic pelvic pain in 40-50-year-old women with endometriosis treated by laparoscopic hysterectomy and salpingoepherectomy compared to conservative laparoscopic surgery

##### Design

A non- randomized clinical trial with two groups of laparoscopic-hysterectomy and conservative laparoscopic surgery, with parallel groups, double-blind, phase 2 on 100 patients.

##### Settings and conduct

This study will be conducted in Hazrat Rasool Akram Hospital. The written consent form is signed and dated. Endometriosis patients undergoing laparoscopic surgery undergo two types of Hysterectomy and salpingovaphectomy and conservative laparoscopy. Study 2 is blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age between 40 and 50 years Do not have surgery related to endometriosis 2. The patient's fertility is complete or she has no intention of fertility Have a 3. vas score above 8 before surgery 4. Failure to respond to three-month analgesic drug treatment  
Exclusion criteria: 1. has an underlying disease (heart, blood pressure, depression, any other type of problem) 2. Age less than 40 years 3. Intends to be fertile, has a history of surgery related to endometriosis 4. Vas score is less than 8

##### Intervention groups

1. The group that undergoes hysterectomy and salpingovaphectomy 2. People who undergo conservative laparoscopic surgery for endometriosis.

##### Main outcome variables

Pain, quality of life and sexual function

#### General information

##### Reason for update

This study was initially designed as a randomized controlled trial, but randomization was not possible due to the ethical obligation to inform patients about the nature and consequences of radical surgery, including hysterectomy. As a result, patients chose their desired surgical approach after comprehensive counseling, which resulted in a practical and preference-based allocation. In addition, in the general information section of the design, it was mentioned from the beginning that randomization was not applicable in the investigator's opinion. Therefore, the randomization protocol was omitted in the abstract section.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191123045476N5**  
Registration date: **2023-11-04, 1402/08/13**  
Registration timing: **registered\_while\_recruiting**

Last update: **2025-09-23, 1404/07/01**

Update count: **1**

##### Registration date

2023-11-04, 1402/08/13

##### Registrant information

###### Name

Samaneh Rokhgireh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6650 9283

###### Email address

rokhgireh.s@iums.ac.ir

##### Recruitment status

**Recruitment complete**

## Funding source

### Expected recruitment start date

2023-10-23, 1402/08/01

### Expected recruitment end date

2024-06-04, 1403/03/15

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

## Scientific title

Investigating the quality of life and chronic pelvic pain in 40-50-year-old women with endometriosis treated by hysterectomy and laparoscopic salpingo-ferectomy compared to conservative laparoscopic surgery.

## Public title

Investigating the quality of life and pain of endometriosis patients treated by hysterectomy and laparoscopy

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age between 40 and 50 years Do not have surgery related to endometriosis The patient's fertility is complete or she has no intention of fertility Have a vas score above 8 before surgery Failure to respond to three-month analgesic drug treatment

### Exclusion criteria:

They have past medical such as hypertension , deprection , Diabet & .... Age less than 40 years Intends to be fertile She has a history of surgery related to endometriosis Vas score is less than 8

## Age

From **40 years** old to **50 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Investigator
- Data analyser

## Sample size

Target sample size: **140**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, the main researcher and the data analyst will be blinded to the assignment of the study groups; The patients are given a special code and the analyst does not know which group A and B are, and the main researcher is not involved in the selection of patients and does not know which group the patient who is undergoing surgery belongs to.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Iran University of medical sciences, Hammat highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

#### Approval date

2022-11-15, 1401/08/24

#### Ethics committee reference number

IR.IUMS.FMD.REC.1401.428

## Health conditions studied

### 1

#### Description of health condition studied

Endometriosis

#### ICD-10 code

N80.0

#### ICD-10 code description

Endometriosis of uterus

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

3 month before surgery and 6 month & 12 month after surgery

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

First Intervention group: The group that undergoes hysterectomy and salpingovaphectomy

### Category

Lifestyle

## 2

### Description

Second Intervention group: People who undergo conservative laparoscopic surgery for endometriosis.

### Category

Lifestyle

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Rasool Akram Hospital

#### Full name of responsible person

Samaneh Rokhgireh

#### Street address

Rasool Akram Hospital, Mansouri Street, Starkhan, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1445613131

#### Phone

+98 21 6650 9283

#### Email

rokhgireh.s@iums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Majid Safa

#### Street address

Iran University of Medical Sciences, Next to Milad tower, Hemmat Highway, Tehran, Iran

#### City

Tehran

#### Province

Tehran

#### Postal code

۱۴۴۹۶۱۴۵۳۵

#### Phone

+98 21 8670 4611

#### Email

safa.m@iums.ac.ir

#### 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

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

Iran University of Medical Sciences

#### Full name of responsible person

Samaneh Rokhgireh

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Hazrat rasool-akram hospital ,Sattarkhan

#### City

Tehran

#### Province

Tehran

#### Postal code

1445613131

#### Phone

+98 21 6650 9283

#### Fax

#### Email

Rokhgireh.s@iums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Samaneh Rokhgireh

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Sattarkhan- hazrat rasool-akram hospital

#### City

Tehran  
**Province**  
Tehran  
**Postal code**  
1445613131  
**Phone**  
+98 21 6650 9283  
**Fax**  
**Email**  
Rokhgireh.s@iums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Samaneh Rokhgireh  
**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
**Street address**  
Sattarkhan- hazrat rasool-akram hospital  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1445613131  
**Phone**  
+98 21 6650 9283  
**Fax**  
**Email**

Rokhgireh.s@iums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

After the article is published, confidential information such as patient and hospital details will be removed and other information will be provided to the researchers.

### When the data will become available and for how long

After publishing the article

### To whom data/document is available

Medical specialists

### Under which criteria data/document could be used

Medical professionals can access the data for research purposes.

### From where data/document is obtainable

Refer to the email of the responsible author (Samaneh Rokhgireh, email: s.rokhgireh@gmail.com )

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

Official and academic email to the responsible author

### Comments