

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