

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of ovarian suspension in preventing post-operative ovarian adhesion in woman with sever endometriosis

Protocol summary

Study aim

Evaluation of recurrence of adhesion after surgery.

Design

70 patients selected using random allocation software are divided into two groups with and without hanging the ovaries. In the software, the total sample size (70 people) and the number of groups (two groups) are entered into the software. .

Settings and conduct

Patients are first examined and history is taken and their personal and clinical information including age, height, weight, body mass index, and endometriosis risk factors are evaluated and recorded in the data collection form. The presence of dysmenorrhea and dyspareunia is also determined and recorded using the Visual Anxiety Scale (VAS). Ovarian hanging was performed randomly in 35 patients and not in 35 patients as a control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women over 18 years with severe endometriosis according to ultrasound, informed consent and women with severe endometriosis need to protect the uterus and ovaries Exclusion criteria: unsuccessful surgery; Patients with surgical complications, lack of follow-up and patient withdrawal from the study

Intervention groups

Patients with severe endometriosis who undergo ovarian hanging in one group and this is not done in the control group.

Main outcome variables

Existence of adhesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120201008897N10**

Registration date: **2022-05-23, 1401/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-23, 1401/03/02**

Update count: **0**

Registration date

2022-05-23, 1401/03/02

Registrant information

Name

Safoura Rouholamin

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of ovarian suspension in preventing post-operative ovarian adhesion in woman with sever endometriosis

Public title

The effect of ovarian suspension in Endometriosis surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women over 18 years of age who are diagnosed with endometriosis + no sliding according to transvaginal ultrasound and history and physical condition Women with severe endometriosis need bilateral dissection and need to protect the uterus and ovaries Patient informed consent to enter the study

Exclusion criteria:

Inability to tolerate transvaginal ultrasound Unsuccessful surgery - Patients who suffer from surgical complications such as intestinal injury, unplanned oophorectomy or change to laparotomy Lack of subsequent patient visits to determine the severity of menstrual pain and postoperative complications The patient refuses to continue attending the study

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The 70 patients selected were randomly assigned to two groups with and without ovarian suspension using randomized allocation software. In the mentioned software, the total number of sample size (70 people) and the number of groups (2 groups) are entered into the software. The software output includes a list that randomly distributes numbers 1 to 70 in two groups. Patients are distributed in two groups according to the time of referral in order to reach the required number of samples in each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is performed by Double blind method. Patients are unaware of the type of operation (without hanging the ovaries and hanging the ovaries); The outcome assessor (sonographer) is also unaware of whether or not the ovaries are suspended.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan Hezar Jerib St. Isfahan University of Medical Sciences and Health Services

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Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-12-31, 1400/10/10

Ethics committee reference number

IR.MUI.MED.REC.1400.720

Health conditions studied

1

Description of health condition studied

severe endometriosis

ICD-10 code

N80.1

ICD-10 code description

Endometriosis of ovary

Primary outcomes

1

Description

check for adhesion

Timepoint

Before surgery and three months after surgery

Method of measurement

Transvaginal ultrasound

Secondary outcomes

1

Description

Severity of dysmenorrhea

Timepoint

Before surgery and three months after surgery

Method of measurement

Visual Analogue Scale

2

Description

Severe dyspareunia

Timepoint

Before surgery and three months after surgery

Method of measurement

Visual Analogue Scale

3**Description**

Severe postoperative pain

Timepoint

Up to three days after surgery

Method of measurement

Visual Analogue Scale

4**Description**

Severity of chronic pelvic pain

Timepoint

Before surgery and three months after surgery

Method of measurement

Visual Analogue Scale

Intervention groups**1****Description**

Intervention group: Women with severe endometriosis, after the release of adhesions during the operation, the ovaries are hung on the anterior wall of the abdomen with vicryl thread and five days later, the ovaries are sutured and released into the abdomen; This period is equivalent to the period of peritoneal repair. Then, three months later, an ultrasound is performed to check for ovarian adhesions.

Category

Treatment - Surgery

2**Description**

Control group: Control group: In women with severe endometriosis and release of adhesions during surgery and release of both ovaries, hanging of the ovaries during surgery is not performed and three months later, ovarian sliding examination is performed.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan Shahid Beheshti hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

safoura rouholamin

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No; The data will not be shared separately, but the results of their analysis will be shared in the article

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available