Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation and comparison of the sclerotherapy and laparoscopic cystectomy on the ovarian reserve and the disease relapse of patients with ovarian endometriosis in university hospitals, Isfahan

Protocol summary

Study aim

Evaluation and comparison of the sclerotherapy and laparoscopic cystectomy on the ovarian reserve and the disease relapse of patients with ovarian endometriosis

Design

A three phase clinical trial with two intervention groups, in parallel, not-blinded, randomized with simple method, with sample size of 70

Settings and conduct

This study is a randomized not-blinded clinical trial in Isfahan University Hospitals. The study population consists of 70 patients with ovarian endometriosis and chronic pelvic pain. Patients are included in the study if they met the inclusion criteria and after giving written consent and then are randomly divided into two groups.The first group will consist of 35 patients undergoing sclerotherapy under sedation with cook needle and the second group will include 35 patients undergoing laparoscopic cystectomy for endometrial lesions.After intervention in both groups, control ultrasound will be performed about 12 weeks later in case of evaluation the recurrence of the lesions. Ovarian follicle reserve is also measured by anti-mullerian hormone (AMH) assay, which may indicate an effect on fertility.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Detection of endometriosis by ultrasound or MRI Patient Satisfaction for Inclusion Ages over 18 years No doubt to malignancy Abnormal amounts of CA125 tumor marker Having infertility Having chronic pelvic pain Ovarian cysts about 4-8 cm Exclusion criteria: Patients whose information is incomplete Non-endometriotic ovarian masses History of any malignancy

Intervention groups

The first group will consist of 35 patients undergoing sclerotherapy under sedation with cook needle and the second group will include 35 patients undergoing laparoscopic cystectomy for endometrial lesions.

Main outcome variables

Recurrence of lesions,ovarian reserve

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N31**
Registration date: **2020-03-05, 1398/12/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-05, 1398/12/15**
Update count: **0**

Registration date

2020-03-05, 1398/12/15

Registrant information

Name
Sadra Ansaripour
Name of organization / entity
Shahrekord University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 3650 3487
Email address
st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation and comparison of the sclerotherapy and laparoscopic cystectomy on the ovarian reserve and the disease relapse of patients with ovarian endometriosis in university hospitals, Isfahan

Public title
Comparison of sclerotherapy and laparoscopic cystectomy on ovarian reserve and disease relapse in patients with ovarian endometriosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Detection of endometriosis by ultrasound or MRI Patient Satisfaction for Inclusion Ages over 18 years No doubt to malignancy Abnormal amounts of CA125 tumor marker Having infertility Having chronic pelvic pain Ovarian cysts about 4-8 cm
Exclusion criteria:
Patients whose information is incomplete Non-endometriotic ovarian masses History of any malignancy
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients in this study are randomly divided into two groups of A and B. In this way, a code is provided for each of the two intervention groups, and patients are randomly assigned to one of the two groups by choosing one of the two codes.
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
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahn University of Medical Sciences, Hezar Jarib st, Isfahan
City
Isfahan
Province
Isfehan
Postal code
7346181746
Approval date
2020-01-04, 1398/10/14
Ethics committee reference number
IR.MUI.MED.REC.1398.499

Health conditions studied

1

Description of health condition studied
Ovarian endometriosis
ICD-10 code
N80.1
ICD-10 code description
Endometriosis of ovary

Primary outcomes

1

Description
Recurrence of endometriosis lesions
Timepoint
12 weeks after interventon
Method of measurement
Sonography

2

Description
Ovarian reserve
Timepoint
12 weeks after interventon
Method of measurement
Measurement of anti-mullerian hormoneserum levels

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: The first group will consist of 35 patients undergoing sclerotherapy with cook needle under sedation. The method of treatment for sclerotherapy is that transvaginal sclerotherapy is performed under sedation and sonography guide and if the surgeon observes endometriosis, the specimen is punctured with a special puncture needle and aspirated. Then about 80% of the volume aspirated up to a maximum of 100 ml from ethanol 95% enters the lesion.The ethanol stays in the lesion for about 20 minutes and then is completely discharged to eliminate ethanol complications. Patients will be monitored for at least 3 hours.

Category

Treatment - Surgery

2

Description

Second intervention group: the second group will include 35 patients undergoing laparoscopic cystectomy for endometrial lesions.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Hatav Ghasemi Tehrani

Street address

Soffeh Boulevard

City

Isfahan

Province

Isfehan

Postal code

7346181746

Phone

+98 31 3445 2031

Email

Hatav.tehrani2014@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Street address

Isfahan University of Medical Sciences, Hezar jarib Avne

City

Isfahan

Province

Isfehan

Postal code

7346181746

Phone

+98 31 3668 0048

Email

farajzadegan@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

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

Hatav Ghasemi Tehrani

Position

Professor of gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Alzahra hospital

City

Isfahan

Province

Isfehan

Postal code

7346181746

Phone

+98 31 3445 2031

Email

Hatav.tehrani2014@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hatav Ghasemi Tehrani

Position

Professor of gynecology

Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Alzahra hospital
City
Isfahan
Province
Isfehan
Postal code
7346181746
Phone
+98 31 3445 2031
Email
Hatav.tehrani2014@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hatav Ghasemi Tehrani
Position
Professor of gynecology
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Alzahra hospital
City
Isfahan
Province
Isfehan
Postal code
7346181746
Phone
+98 31 3445 2031
Email
Hatav.tehrani2014@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available