

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of Ovarian Reservation in Women with Endometriosis under Total Cystectomy Compared to Partial Cystectomy

Protocol summary

Study aim

Evaluation of Ovarian Reservation in Women with Endometriosis under Total Cystectomy compared to Partial Cystectomy

Design

A randomized, double-blind, clinical trial with two parallel intervention groups design of 56 patients (phase 3). The table of random numbers was used for randomization.

Settings and conduct

The subjects were selected from among patients with ovarian endometriosis referred to Shahid Sadoughi Hospital in Yazd according to the criteria for entering the study. The diameter of the cyst is measured using vaginal ultrasound or MRI, and in cases of bilateral endometriosis, the total size of the two cysts is considered. Patients will be divided into two groups and randomly divided into two groups using the table of random numbers. One group underwent total cystectomy and the other group underwent partial cystectomy. The amount of anti-müllerian hormone in both groups is measured by ELISA before and 3 months after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age between 20 and 40 years 2- Serum level of anti-Müllerian hormone (AMH) over than 1 ng/mL 3- Endometrioma cyst larger than 4 cm Exclusion criteria: 1- Pregnancy 2- Menstrual bleeding disorder 3- Endocrine disorders include thyroid disorder, hyperprolactinemia, or Cushing's syndrome 4- History of ovarian surgery and surgeries that have altered the anatomy of the pelvic cavity 5- Serum level of follicle stimulating hormone (FSH) level around menopause 6- Suspicion of ovarian malignancies 7- Take oral contraceptive pills (OCPs) three months before surgery

Intervention groups

Intervention group I: under total cystectomy Intervention group II: under partial cystectomy

Main outcome variables

The serum level hormone anti-müllerian hormone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046993N2**

Registration date: **2020-05-26, 1399/03/06**

Registration timing: **retrospective**

Last update: **2020-05-26, 1399/03/06**

Update count: **0**

Registration date

2020-05-26, 1399/03/06

Registrant information

Name

Atiyeh Javaheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-14, 1398/10/24

Expected recruitment end date

2020-02-13, 1398/11/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Ovarian Reservation in Women with Endometriosis under Total Cystectomy Compared to Partial Cystectomy	
Public title	The effect of total cystectomy surgery versus parietal cystectomy on the ovarian reservation
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Age between 20 to 40 years old Serum level of anti-Müllerian hormone (AMH) over than 1 ng/mL Endometrioma cyst larger than 4 cm Exclusion criteria: Pregnancy Menstrual bleeding disorder Endocrine disorders include thyroid disorder, hyperprolactinemia, or Cushing's syndrome History of ovarian surgery and surgeries that have altered the anatomy of the pelvic cavity The serum level of follicle stimulating hormone (FSH) around menopause Suspicion of ovarian malignancies Take oral contraceptive pills (OCPs) three months before surgery
Age	From 20 years old to 40 years old
Gender	Female
Phase	3
Groups that have been masked	No information
Sample size	Target sample size: 56
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, in people before surgery, the concentration of antimullerin hormone is measured by ELISA method and after grouping endometriosis in them, by using simple randomization method with individual unit and by using the table of random numbers of people in The two groups of partial and total cystectomy are operated on, and all patients are operated on by one surgeon to minimize the difference in surgical technique.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	Name of ethics committee Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences Street address School of Medicine, Shahid Sadoughi University of Medical Sciences, Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran City Yazd Province Yazd Postal code ۸۹۱۵۱۷۳۱۳۳ Approval date 2020-01-14, 1398/10/24 Ethics committee reference number IR.SSU.MEDICINE.REC.1398.296
Health conditions studied	
<u>1</u>	
Description of health condition studied	Endometriosis
ICD-10 code	N80.1
ICD-10 code description	Endometriosis of ovary
Primary outcomes	
<u>1</u>	
Description	The serum level of anti-müllerian hormone
Timepoint	At the beginning of the study (Before intervention) and 3 months after the intervention (Cystectomy)
Method of measurement	Eliza's method
<u>2</u>	
Description	The serum CA125 level
Timepoint	At the beginning of the study (Before intervention)
Method of measurement	Eliza's method
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Intervention group 1: In this group, total cystectomy surgery was performed in which patients underwent general anesthesia and endotracheal intubation in 30

degree Thunderrenberg condition and lithotomy, and carbon dioxide gas was opened by a 10 mm trocar with open method And 10 mm Hg pressure and under the supervision of a 10 mm rigid laparoscope inserted through the umbilical port and 2 other 5 mm ports created 2 cm above the iliac bone and a uterine manipulator placed inside the patient's uterus. If necessary, the Keldosak area was released, then the cyst was aspirated and emptied, and the adhesion between the cyst and the pelvic wall was released, and then the internal wall of the cyst was gently separated from the normal ovarian cortex by two atromatic pliers. In all patients, the presence of endometriosis was confirmed by pathology, and the antimullerin levels of the hormone were examined before and 3 months after the operation.

Category

Treatment - Surgery

2

Description

Intervention group 2: In this group, partial cystectomy surgery was performed. In this method, patients underwent general anesthesia and endotracheal intubation in 30 degree Thunderrenberg condition and in lithotomy status, and carbon dioxide gas by a 10 mm trocar with open method and pressure 10 mmHg under the supervision of a 10 mm rigid laparoscope inserted through the umbilical port, two other 5 mm ports created 2 cm above the iliac bone, and a uterine manipulator placed inside the patient's uterus. If necessary, the Keldosak area was released, then the cyst was aspirated and emptied, and the adhesion between the cyst and the pelvic wall was released. The umbilical cord remains the ovary. In all patients, the presence of endometriosis was confirmed by pathology, and the antimullerin levels of the hormone were examined before and 3 months after the operation.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Shahid Sadoghi Hospital

Full name of responsible person

Atiyeh Javaheri

Street address

Shahid Sadoughi hospital, Ebne- Sina Ave., Yazd, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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Bahonar Sq., Shahid Sadoughi Ave., Shahid Sadoughi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Atiyeh Javaheri

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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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