# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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-mullerian 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**

+98 35 3183 4284

**Email address**

a.javaheri@ssu.ac.ir

**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

**1**

**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**
۸۹۱۵۱۷۳۱۴۳
**Approval date**
2020-01-14, 1398/10/24
**Ethics committee reference number**
IR.SSU.MEDICINE.REC.1398.296

## Health conditions studied

**1**

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

## Primary outcomes

**1**

**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

**2**

**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

**1**

**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

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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 University of Medical Sciences, Yazd

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mmirzaei@ssu.ac.ir

**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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## Person responsible for updating data

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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