

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of ovarian reserve before and after laparoscopic cystectomy in patients with ovarian cyst in need of surgery.

Protocol summary

Study aim

Ovarian Reserve Assessment Before and After
Laparoscopic Cystectomy

Design

Clinical trial on 90 patients.no blinded

Settings and conduct

This study will be performed on 90 patients with ovarian cysts in reproductive ages 15-35 years who refer to Al-Zahra Hospital in Tabriz and undergo laparoscopic resection of ovarian cysts due to the need for surgery. The combination of suturing and electrocoagulation with bipolar instruments will be used to control homeostasis, so that the minimum amount of ovarian cautery will be used to prevent ovarian reserve loss, and where necessary, sutures will be used to control homeostasis.)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women at fertility age between 15 and 35 years; with ovarian cysts 3 to 10 cm in size and requiring surgery. Non-inclusion criteria: Evidence of ovarian cancer; Menopause; Pregnant patients; Patients with advanced chronic diseases; Before menarche; Ovarian torsion

Intervention groups

Ninety patients diagnosed with non-endometrioma ovarian cysts will undergo laparoscopic ovarian cyst resection surgery. All surgeries in this study will be performed by a gynecologist. Combination of suctioning and electrocoagulation with bipolar instruments will be used to control homeostasis. The minimum amount of ovarian cautery will be used to prevent the loss of ovarian reserve, and where necessary, suture will be used to control homeostasis.

Main outcome variables

Serum levels of antimullerian hormone (AMH); Serum levels of follicle-stimulating hormone (FSH); Ovarian volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211103052950N2**

Registration date: **2022-02-09, 1400/11/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-09, 1400/11/20**

Update count: **0**

Registration date

2022-02-09, 1400/11/20

Registrant information

Name

Fatemeh Tabatabaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3326 2754

Email address

drtabatabaeigyn@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of ovarian reserve before and after laparoscopic cystectomy in patients with ovarian cyst in need of surgery.

Public title

Ovarian Reserve Assessment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women at fertility age between 15 and 35 years With ovarian cysts 3 to 10 cm in size and requiring surgery

Exclusion criteria:

Evidence of ovarian cancer Post menopausal patients Pregnant patients History of multiple previous surgeries in more than two time Patients with advanced chronic diseases For any reason that the operation turns into a laparotomy Before menarche Ovarian torsion

Age

From **15 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences

Street address

Third Floor, Central Building Number 2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2021-12-13, 1400/09/22

Ethics committee reference number

IR.TBZMED.REC.1400.912

Health conditions studied

1

Description of health condition studied

Ovarian cyst

ICD-10 code

N83.0

ICD-10 code description

Follicular cyst of ovary

Primary outcomes

1

Description

Ovarian Reserve

Timepoint

The third day of the last menstrual cycle before surgery - six months after surgery - one year after surgery

Method of measurement

laboratory kit

2

Description

Serum levels of antimullerian hormone (AMH)

Timepoint

The third day of the last menstrual cycle before surgery - six months after surgery - one year after surgery

Method of measurement

laboratory kit

3

Description

Serum level of FSH (follicular stimulating hormon)

Timepoint

The third day of the last menstrual cycle before surgery - six months after surgery - one year after surgery

Method of measurement

laboratory kit

Secondary outcomes

1

Description

Ovarian Volume

Timepoint

Two weeks after surgery - Six months after surgery - One year after surgery

Method of measurement

Ultrasound measurement of ovarian volume

Intervention groups

1

Description

Ninety patients diagnosed with non-endometrioma ovarian cysts will undergo laparoscopic ovarian cyst resection surgery. All surgeries in this study will be performed by a gynecologist. Combination of suctioning and electrocoagulation with bipolar instruments will be used to control homeostasis. The minimum amount of ovarian cautery will be used to prevent the loss of ovarian reserve, and where necessary, suture will be used to control homeostasis.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital of Tabriz

Full name of responsible person

Fatemeh Tabatabaei

Street address

Alzahra Hospital , Artesh Street, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Parviz Shahabi

Street address

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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5138665793

Phone

+98 41 3335 7310

Email

research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Research,Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Tabatabaei

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after making individuals unidentifiable

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions and people who working in industry

Under which criteria data/document could be used

By observing the principle of intellectual property and without making any changes or misapplication

From where data/document is obtainable

Scientific respondent to the study E-mail : drtabatabaeigyn@gmail.com Dr. Fatemeh Tabatabaei

What processes are involved for a request to access data/document

Will be answered in less than two weeks

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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