

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of the morbidity after laparoscopic surgery of ovarian endometrioma in patients with ovary suturing and control group: a randomization clinical trial

Protocol summary

Summary

The aim of this study was to compare morbidity and mortality in suturing ovary compared with non-use of suture. This study will be conducted as a clinical trial multi-centric. Inclusion criteria included women of reproductive age undergoing laparoscopic ovarian cystectomy, and exclusion criteria included patients with diabetes, immune deficiency, coagulation disorders and pathology report is suggestive of malignant ovarian cyst wall. The study population included women undergoing laparoscopic cholecystectomy larger than five centimeters ovarian referred to Hazrat-e-Rasoul and Pars Hospital barking, and sample size in this study is 82 Patients. After confirming the inclusion criteria and obtain the written consent of the individual, Use the table of random numbers into random groups have suture and non-suture. Ovarian cystectomy, laparoscopic surgery were randomly and ovaries surgically sutured with thread measurable in this study include measuring the amount of hemoglobin drop. fever ovarian reserve is allocated. Surgery by doctors at the hospital will be fixed. Measurement of anti-Mullerian hormone levels hemoglobin levels six hours after surgery blood in the third period and also to investigate the occurrence of fever after surgery to check for sublingual temperature every eight hours after the surgery is done if the readmission during the first six weeks after surgery control the patient's fever and hemoglobin concentration, respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090923949N1**

Registration date: **2016-02-01, 1394/11/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-01, 1394/11/12

Registrant information

Name

Mansoureh Vahdat

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the morbidity after laparoscopic surgery of ovarian endometrioma in patients with ovary suturing and control group: a randomization clinical trial

Public title

Comparison of the morbidity after laparoscopic surgery

of ovarian endometrioma in patients with ovary suturing and control group (without ovary suturing).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: women in reproductive age candidate for laparoscopic cystectomy for endometrioma Exclusion criteria: Diabetes, immune deficiency, coagulopathy, malignancy in pathological exam

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 82

Randomization (investigator's opinion)

Randomized

Randomization description

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 Iran University of Medical Science

Street address

Iran . Tehran . Hemat Highway . Milad Tower

City

Tehran

Postal code

Approval date

2015-04-19, 1394/01/30

Ethics committee reference number

IR.IUMS.REC.1394.25324

Health conditions studied

1

Description of health condition studied

Ovarian cysts

ICD-10 code

N83.2

ICD-10 code description

Other and unspecified ovarian cysts

Primary outcomes

1

Description

Hemoglobin rate

Timepoint

One day before surgery and 6 hours after surgery.

Method of measurement

Bleeding sample

Secondary outcomes

1

Description

Hospital admission days

Timepoint

The 6 week after surgery.

Method of measurement

Day

2

Description

Fever

Timepoint

The 6 week after surgery.

Method of measurement

Thermometer

3

Description

Anti Mullerian hormone

Timepoint

The before surgery and third period after surgery.

Method of measurement

Bleeding sample

Intervention groups

1

Description

The intervention is suturing the ovary tissue by inverting the ovary wedgs using Vicryl 2-0

Category

Treatment - Surgery

2

Description

In control group not suturing the ovary tissue

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul e akram hospital

Full name of responsible person

Dr. Mansoureh vahdat

Street address

Niayesh Av. Sattar khan St. Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Pars general hospital

Full name of responsible person

Abolfazal Mehdizadeh kashi

Street address

No11, saeedi Alley, fereshteh St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Ali Javad Musavi

Street address

Research Deputy office of Iran University of Medical Sciences

City

Tehran

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

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Position

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Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty