

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparative Study of the Effect of "Electrocautery" and "Suture" Homeostasis on Laparoscopic non-endometriotic benign Ovarian Cyst on Mean Anti mullerian Hormone Levels

#### Protocol summary

##### Study aim

1. Determination and Comparison of the Effect of "Electrocautery" and "Suture" Hemostasis Methods on Laparoscopic non-endometriotic Benign Ovarian Cysts on Mean Anti Mullerian Hormone Levels 2. Determination and Comparison of Mean Anti Mullerian Hormone Levels in Two Groups of Patients (Hemostasis with Electrocautery and Suture) before and Three Months after Laparoscopic Cystectomy

##### Design

A clinical trial with randomized parallel groups; total sample size 50 patients

##### Settings and conduct

Individuals of Reproductive Age who are Candidates for Excision of Non-endometriotic Ovarian Cysts with Laparoscopic Benign Features are Identified. Patients'AMH and Hemoglobin Levels in these Patients are Measured Preoperatively in a Single Center at Al-Zahra Hospital Laboratory. Intraoperative Bleeding will be Control Randomly using a Bi-polar or Suture. Patients will also be Monitored for Hemoglobin 24 hours after Surgery and will be Measured and AMH was Recorded again three Months after Surgery.

##### Participants/Inclusion and exclusion criteria

Informed Consent, Ages 15 to 42, Having Criteria for Ovarian Cyst Removal; Malignant Ovarian Cysts, Ovarian Endometriotic Cysts, History of Malignant Disease and Receiving Chemotherapy, History of Ovarian Surgery, Patients with a History of Illness and Coagulation Problems

##### Intervention groups

Randomly Controlled Bleeding by Cutter or Suture And Comparison of the Effect of Two Methods on Mean Level of Anti-Mullerian Hormone

##### Main outcome variables

Evaluation of the Better Effectiveness of "Electrocautery" and "Suture" Hemostasis on Mean Anti Mullerian

Hormone Levels

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200113046116N1**

Registration date: **2020-02-08, 1398/11/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-08, 1398/11/19**

Update count: **0**

##### Registration date

2020-02-08, 1398/11/19

##### Registrant information

##### Name

Mahsa Tavoli

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3273 0922

##### Email address

mehdikhosravi29@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-04, 1398/11/15

##### Expected recruitment end date

2020-06-19, 1399/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparative Study of the Effect of "Electrocautery" and "Suture" Homeostasis on Laparoscopic non-endometriotic benign Ovarian Cyst on Mean Anti mullerian Hormone Levels

**Public title**

Comparison of "Electrocautery" and "Suture" Mean Anti mullerian Hormone Levels

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Individuals who entered the study with informed consent  
People aged 15 to 42 years  
The patient has criteria for removal of the ovarian cyst

**Exclusion criteria:**

Ovarian malignant cysts  
Ovarian endometriotic cysts  
A history of malignant diseases and receiving chemotherapy  
People with a history of ovarian surgery  
Patients with a history of illness and coagulation problems

**Age**

From **15 years** old to **42 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Not 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 of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8154735811

**Approval date**

2019-05-08, 1398/02/18

**Ethics committee reference number**

IR.MUI.MED.REC.1397.329

**Health conditions studied****1****Description of health condition studied**

"electrocautery" , "suture" , laparoscopic non-endometriotic benign ovarian cyst ,mean Anti mullerian hormone levels

**ICD-10 code**

N83.2

**ICD-10 code description**

Other and unspecified ovarian cysts

**Primary outcomes****1****Description**

Mean anti mullerian hormone levels

**Timepoint**

Before surgery and 3 months after surgery

**Method of measurement**

with cobas411 device

**Secondary outcomes****1****Description**

Hemoglobin level

**Timepoint**

Before surgery and the day after surgery

**Method of measurement**

Test

**Intervention groups****1****Description**

Intervention group: homeostasis with suture. After laparoscopic benign ovarian cyst removal, patients underwent a suture for homeostasis and preoperative and 3 months postoperative antimalarial hormone levels were measured by Kobas mMachine in Al-Zahra hospital laboratory.

**Category**

Treatment - Devices

## 2

### Description

Intervention group: homeostasis with electrocautery. After laparoscopic benign ovarian cyst removal, patients underwent cutter for homeostasis and preoperative and 3 months postoperative antimalarial hormone levels were measured by Kobas machine in Al-Zahra hospital laboratory.

### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Al Zahra hospital

**Full name of responsible person**

Mahsa Tavoli

**Street address**

Sofeh Ave, Al Zahra hospital

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8154735811

**Phone**

+98 31 3273 0922

**Email**

mehdikhosravi29@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Shaghaegh Haghjoo

**Street address**

Hezar Jerib Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Phone**

+98 31 3668 8138

**Email**

research@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**

Mahsa Tavoli

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Al Zahra hospital, Sofeh Ave.

**City**

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**Province**

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**Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

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Mahsa Tavoli

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Resident

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

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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 Can be Shared, After Patients are

Unrecognizable

**When the data will become available and for how long**

Start of Access Period from 1399

**To whom data/document is available**

All Interested People

**Under which criteria data/document could be used**

Commitment to Mention the Main Source

**From where data/document is obtainable**

Mahsa Tavoli, mehdikhosravi29@yahoo.com

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

Send Request by Email

**Comments**