

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The comparison of ovarian reserve after laparoscopic cystectomy of endometrioma using bipolar electrocoagulation versus intracorporeal suture: Clinical trial study

#### Protocol summary

##### Summary

This study is an interventional clinical trial, in order to determine and implement the best techniques for hemostasis in patients with endometrioma cystectomy that surgery necessity is diagnosed for them. Inclusion criteria for our study are patients aged 18-42 years, regular menstrual cycles with ovarian endometrioma, complaining of dysmenorrhea, infertility or pelvic mass for whom surgery is considered necessary. Exclusion criteria is also a history of ovarian surgery, pelvic inflammatory disease, previous chemotherapy or endocrine diseases (such as diabetes or hyper prolactinoma). Anti-Mullerian hormone levels, estradiol and FSH on the third day of the menstrual cycle before surgery are measured. The laparoscopic cystectomy performed on patients using atraumatic graspers then hemostasis with bipolar electrocoagulation or suturing technique, randomly was done by a surgeon. The number of calculated samples in each group is 44. Again 3 months after surgery, the laboratory tests on the third day of the menstrual cycle will be measured. The post operative results of anti-Mullerian hormone, estradiol, and FSH with preoperative values in both groups (surgical hemostasis with bipolar and suturing) and also between the two groups will be compared. Then, these comparisons should be interpreted.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201403088897N2**

Registration date: **2014-04-13, 1393/01/24**

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

Last update:

Update count: **0**

##### Registration date

2014-04-13, 1393/01/24

##### Registrant information

###### Name

Safoura Rouholamin

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1236 7001

###### Email address

s\_rouholamin@med.mui.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2013-12-22, 1392/10/01

##### Expected recruitment end date

2014-08-22, 1393/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of ovarian reserve after laparoscopic cystectomy of endometrioma using bipolar electrocoagulation versus intracorporeal suture: Clinical trial study

##### Public title

Evaluation of ovarian reserve after laparoscopic cystectomy of endometrioma

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: patients 18-42 years old who candidate for surgery because of dysmenorrhea, suspicious endometrioma or infertility Exclusion criteria: Previous history of ovarian surgery or pelvic surgery; Previous endocrinology disease (DM, hyperprolactinoma and thyroid disease); pelvic inflammatory disease (PID); Previous history of chemotherapy

## Age

From **18 years** old to **42 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **88**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Pourcina St, Keshavars Bul, Meical faculty

##### City

Tehran

##### Postal code

1417614411

#### Approval date

2014-01-27, 1392/11/07

#### Ethics committee reference number

24207-30-03-92

## Health conditions studied

### 1

#### Description of health condition studied

Endometrioma

#### ICD-10 code

N80.1

#### ICD-10 code description

Endometriosis of ovary

## Primary outcomes

### 1

#### Description

Anti mullerian hormone

#### Timepoint

One cycle before and 3 cycle after surgery

#### Method of measurement

ng/ml

### 2

#### Description

FSH

#### Timepoint

One cycle before and 3 cycle after surgery

#### Method of measurement

U/L

### 3

#### Description

Estradiol

#### Timepoint

One cycle before and 3 cycle after surgery

#### Method of measurement

U/L

## Secondary outcomes

### 1

#### Description

HB

#### Timepoint

Before and 24 hours after surgery

#### Method of measurement

gr/dl

## Intervention groups

### 1

#### Description

Cystectomy of endometrioma and controle of hemostasis with bipolar electrocoagulation

#### Category

Treatment - Surgery

### 2

#### Description

Cystectomy of endometrioma and controle of hemostasis with suturing

#### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Arash Hospital, Laparoscopic Ward

**Full name of responsible person**

Safoura Rouholamin

**Street address**

Arash Hospital, Rashid St, Tehranpar

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Khalilpour

**Street address**

Poorcina street, Keshavars Bul, Medical Faculty

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra Asgari

**Position**

Associated professor

**Other areas of specialty/work**

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Arash hospital, Rashid St, Tehranpars

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Assistant professor of Isfahan medical university

**Full name of responsible person**

Safoura Rouholamin

**Position**

Obstetrics and Gynecologist, Laparoscopic flowship

**Other areas of specialty/work**

**Street address**

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**Web page address**

## Person responsible for updating data

### Contact

## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*