

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of ovarian reserve after laparoscopic cystectomy of endometrioma with and without vasopressin injection

#### Protocol summary

##### Summary

This study is a clinical trial to evaluate the level of Antimullerian Hormone Changes in patients with laparoscopic cystectomy of endometrioma with and without vasopressin injection. Sixty six patients with endometrioma that candidate for surgical treatment would be randomly divided into two numerical equal groups. Surgery will be done for one group without vasopressin injection and for the other with vasopressin injection (20 units of vasopressin would be diluted in 200cc of normal saline and then injected in 3 points, each point 3cc, located between ovarian cortex and the cyst wall). Inclusion criteria: women 20 to 42 years with unilateral endometrioma cyst that candidate for surgical treatment . Exclusion criteria: history of ovarian surgery; history of chemotherapy; any diagnosed endocrine disease (diabetes) ;medical treatment for endometrioma during last 3 months . Staging, endometrioma size and location, being environmental or its central, affected ovary and disease stage would be recorded. Blood sampling would be done for measuring AMH by ELISA before and 6 months after surgery to predict ovarian reserve.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201608018897N4**

Registration date: **2016-11-15, 1395/08/25**

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

Last update:

Update count: **0**

##### Registration date

2016-11-15, 1395/08/25

##### 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

Vice Chancellor for Research of Isfahan university of medical Sciences

##### Expected recruitment start date

2015-05-22, 1394/03/01

##### Expected recruitment end date

2016-12-20, 1395/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of ovarian reserve after laparoscopic cystectomy of endometrioma with and without vasopressin injection

##### Public title

The effect of vasopressin on ovarian reserve in cystectomy of endometrioma

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: women 20 to 42 years with unilateral endometrioma cyst; no medical treatment for endometrioma during last 3 months; Lack of any

diagnosed endocrine disease (diabetes, hyperprolactinemia, thyroid disorder); No history of ovarian surgery; No history of chemotherapy. Exclusion criteria: Lack of consent to participate in the study; any pelvic adhesions that prevent complete removal of the cyst; lack of second AMH measure.

#### Age

From **20 years** old to **42 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **66**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical Sciences, Hezarjerib Street

##### City

Isfahan

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

395171

## 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 hormon

#### Timepoint

Before surgery and 6 months after surgery

#### Method of measurement

ELISA

## Secondary outcomes

### 1

#### Description

HB

#### Timepoint

Before and 24 hours after surgery

#### Method of measurement

gr/dl

## Intervention groups

### 1

#### Description

intervention group: 20 units of vasopressin would be diluted in 200cc of normal saline and then injected in 3 points, each point 3cc, located between ovarian cortex and the cyst wall

#### Category

Treatment - Drugs

### 2

#### Description

control group: usual laparoscopic cystectomy of endometrioma

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital

##### Full name of responsible person

Safoura Rouhoamin

##### Street address

Shahid Beheshti Hospital, Motahari Street, Felezi Bridge

##### City

Isfahan

### 2

#### Recruitment center

##### Name of recruitment center

Alzahra Hospital

**Full name of responsible person**

Safoura Rouholamin

**Street address**Alzahra Hospital, Boulevard Shohadaye Sofe, Three  
Hakim Nezami**City**

Isfahan

Bridge

**City**

Isfahan

**Postal code****Phone**

+98 31 3236 7001

**Fax****Email**

Farzaneahmadpour@yahoo.com

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice President of Research of Isfahan University of  
Medical Sciences**Full name of responsible person**

Dr mehdi nematbakhsh

**Street address**Isfahan University of Medical Sciences, Hezarjerib  
Street**City**

Isfahan

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

Yes

**Title of funding source**Vice President of Research of Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Farzane Ahmadpour Qazvini

**Position**

Resident of Obstetrics and Gynecology

**Other areas of specialty/work****Street address**

Shahid Beheshti Hospital, Motahari Street, Felezi

**Person responsible for scientific  
inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Safoura Rouholamin

**Position**

Laparoscopic Fellowship

**Other areas of specialty/work****Street address**Shahid Beheshti Hospital, Motahari Street, Felezi  
Bridge**City**

Isfahan

**Postal code****Phone**

+98 31 3236 7001

**Fax****Email**

s\_rouholamin@med.mui.ac.ir

**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*