

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Comparison of ovarian reserve in laparoscopic endometrioma surgery with and without vasopressin injection

#### Protocol summary

##### Study aim

Determination and comparison of ovarian reserve in laparoscopic endometrioma surgery with and without vasopressin injection

##### Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 44 patients

##### Settings and conduct

In this randomized double-blind randomized clinical trial study, 44 women of reproductive age with endometrioma referred to Shahid Beheshti Hospital in Isfahan will be included in the study and will be randomly divided into 2 groups. One group will receive vasopressin and the other group will receive a placebo.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include diagnosis of unilateral ovarian endometrioma by ultrasound, the size of the cyst should be between 30 and 70 mm, lack of evidence of ovarian cancer, normal menstrual cycle, and individuals with symptomatic endometrioma and surgical indications. Exclusion criteria include patient's pregnancy, body mass index above 30 kg/m<sup>2</sup>, history of any malignancy, detection of ovarian cysts other than endometrioma after surgery, atypical endometrioma, history of kidney, liver, and heart diseases, use of combined contraceptive pills before surgery, previous surgery of endometrioma, and polycystic ovary syndrome.

##### Intervention groups

Intervention group: In this group, 20 units of diluted vasopressin will be diluted by 200 times during surgery. The mentioned injection will be followed by 30-40 ml of normal saline will be injected into the ovaries in different spaces. Control group: In this group, the first 3 ml of normal saline will be injected in one to three points similar to those of the intervention group, and then another 30-40 ml of normal saline will be injected into the ovarian space completely similar to that of the intervention group.

##### Main outcome variables

Number of antral ovarian follicles; Serum levels of anti mullerian hormone

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200825048515N26**

Registration date: **2021-03-30, 1400/01/10**

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

Last update: **2021-03-30, 1400/01/10**

Update count: **0**

##### Registration date

2021-03-30, 1400/01/10

##### Registrant information

##### Name

Asieh Maghami Mehr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 0000 0000

##### Email address

asimaghami@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-21, 1400/01/01

##### Expected recruitment end date

2021-05-21, 1400/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of ovarian reserve in laparoscopic endometrioma surgery with and without vasopressin injection

**Public title**

Comparison of ovarian reserve in laparoscopic endometrioma surgery with and without vasopressin injection

**Purpose**

Treatment

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

Diagnosis of unilateral ovarian endometrioma by ultrasound The size of the cyst should be between 30 and 70 mm Lack of the evidence of ovarian cancer Normal menstrual cycle Individuals with symptomatic endometrioma and surgical indications (infertility, failed assisted reproductive technology (ART) treatment cycles, pelvic pain)

**Exclusion criteria:**

Patient's pregnancy Body mass index above 30 kg/m<sup>2</sup> History of any malignancy Detection of ovarian cysts other than endometrioma after surgery Atypical endometrioma History of kidney, liver, and heart diseases (hypertension - cardiac arrhythmia - ischemia) Use of combined contraceptive pills before surgery (over the last three months) Previous surgery of endometrioma Polycystic ovary syndrome

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

En In this study, 44 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". We randomly divide these numbers into two parts. Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, vasopressin and placebo are pre-prepared and placed in coded packages, and delivered daily to the

relevant specialist. She prescribes them without knowing the type of each drug. Also, the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention.

**Placebo**

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**

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8179964167

**Approval date**

2021-02-15, 1399/11/27

**Ethics committee reference number**

IR.MUI.MED.REC.1399.1046

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

Ovarian endometrioma

**ICD-10 code**

N80.1

**ICD-10 code description**

Endometriosis of ovary

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

Number of antral ovarian follicles

**Timepoint**

Before and three months after surgery

**Method of measurement**

Transvaginal ultrasound

**2****Description**

Serum levels of anti mullerian hormone

## Timepoint

Before and three months after surgery

## Method of measurement

Kit made by Biomeriux company

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, 20 units of diluted vasopressin (Elixir Pharmaceutical Company) will be diluted by 200 times (0.1 units per ml) during surgery. 3 ml of diluted vasopressin will be injected at one to three points near the great vessels, with the exception of the area of the ovarian hilus, and between the cyst space and the ovarian parenchyma, so that 0.3 units of vasopressin will be used for each patient. The mentioned injection will be followed by 30-40 ml of normal saline will be injected into the ovaries in different spaces for the hydro dissection and the prevention of vasopressin complications including arrhythmias.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: In this group, first 3 ml of normal saline will be injected in one to three points similar to those of the intervention group, and then another 30-40 ml of normal saline will be injected into the ovarian space completely similar to that of the intervention group.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Beheshti Hospital

##### Full name of responsible person

Safoura Rouholamin

##### Street address

Motahari Street.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3234 6338

##### Email

s\_rouholamin@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjoo Javanmard

##### Street address

Vice Chancellor for Research, School of Medicine,  
Hezar Jarib Street, Isfahan.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 8597

##### Email

dean@med.mui.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Isfahan 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

Safoura Rouholamin

##### Position

Associate Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Department of Obstetrics and Gynecology, Al-Zahra  
Hospital, Sofeh Blvd., Tohid Street

##### City

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##### Province

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##### Postal code

8174675731

**Phone**

+98 31 3620 2020

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s\_rouholamin@med.mui.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Safoura Rouholamin

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Neda Moghare abed

**Position**

Non-faculty sub-specialist

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Department of Obstetrics and Gynecology, Al-Zahra Hospital, Sofeh Blvd., Tohid Street

**City**

Isfahan

**Province**

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8174675731

**Phone**

+98 31 3620 2020

**Email**

moghreabed@yahoo.com

**Sharing plan**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available