

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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/m², 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/m² 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

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

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

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

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

s_rouholamin@med.mui.ac.ir

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

Isfahan

Postal code

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