

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)

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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

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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
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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**

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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