

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

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

Protocol summary

Summary

Objectives: The aim of this study is assessing the ovarian reserve after laparoscopic cystectomy of endometrioma with and without vasopressin injection. **Setting:** This is a not Blind- randomized, controlled, single center trial. **Inclusion criteria** are patients in 18 - 40 years old with menstruation and ovarian problems in terms of endometrioma- pelvic problem. **Exclusion criteria** are previous ovarian surgery or any pelvic adhesion, underlying endocrine disease and history of chemotherapy. **Intervention:** Before the surgery the level of Anti-Mullerian Hormone FSH, LH and Estradiol will be measured in all patients. Then patients randomly will be divided in two groups. In control group, cystectomy will be done routinely. In intervention group during cystectomy, 20 units of vasopressin will be injected between cortex and cyst edge in 3 locations and then the cyst will be removed. After 3 months blood factors will be measured again and ovarian reserve will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030126855N1**

Registration date: **2016-04-06, 1395/01/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-04-06, 1395/01/18

Registrant information

Name

Maryam Razavi

Name of organization / entity

Tehran university of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2016-04-19, 1395/01/31

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

effect of vasopressin on ovarian reserve after cystectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between 18 to 40 years old; with menstruation; with endometrioma; pelvic problems

Exclusion criteria: history of ovarian surgery; pelvic adhesion; underlying endocrine disease; history of chemotherapy

Age

From **18 years** old to **40 years** old

Gender

Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization: The sequence of treatment will be written on 64 cards. Cards placed inside the envelopes. Random 10-digit code is written on each envelope. When a qualified patient is announced by the surgeon, the methodologist puts envelope in his possession.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Science

Street address
Tehran University of Medical Science, Keshavarz Boulevard, Qods Street

City
Tehran

Postal code

Approval date
2016-01-24, 1394/11/04

Ethics committee reference number
IR.TUMS.REC.1394.1734

Health conditions studied

1

Description of health condition studied
ovarian reserve

ICD-10 code
S37.4

ICD-10 code description
Injury of ovary

Primary outcomes

1

Description
FSH

Timepoint
before and 3 months after surgery

Method of measurement
ELIZA kit

2

Description
anti mullerian hormone

Timepoint
before and 3 months after surgery

Method of measurement
ELIZA kit

3

Description
LH

Timepoint
before and 3 months after surgery

Method of measurement
ELIZA kit

4

Description
esteradiol

Timepoint
before and 3 months after surgery

Method of measurement
ELIZA kit

Secondary outcomes

empty

Intervention groups

1

Description
Control group : After general anesthesia, cyst is taken by kocher and cut with scissors. Cysts and ovarian cortex between the wall surface is separated.

Category
Treatment - Surgery

2

Description
Intervention group: Cystectomy is done similar to control group. During cystectomy, 20 units of vasopressin will be injected between cortex and cyst edge.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash women hospital

Full name of responsible person

Dr.Maryam Razavi

Street address

Arash women hospital, Rashid street, Resalat highway, Tehranpars

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science, research deputy

Full name of responsible person

Dr Masoud Younesian

Street address

Tehran University of Medical Science, Keshavarz boulevard, Qods street,

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 Science, research deputy

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 Science, Arash women hospital

Full name of responsible person

Maryam Razavi

Position

women specialist

Other areas of specialty/work

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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