

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Assessment of the effect of Vasopressin injection on decreasing time of surgery and need to electrocoagulation for hemostasis during laparoscopic cystectomy of patients referred to Zanan Hospital because of endometriomas

Protocol summary

Summary

The aim of this prospective study is to assess the effect of vasopressin in reducing time of surgery and need for coagulation for hemostasis during laparoscopic cystectomy for endometrioma. The inclusion criteria are unilateral ovarian endometrioma (4-7 centimeters) and age 18-35 years old. The exclusion criteria are prior ovarian surgery and usage of oral contraceptive before surgery. According to these criteria 14 female randomly would be put inside 2 separate groups of 7 persons; first group undergoes laparoscopic cystectomy with hydrodissection with normal saline and second group undergoes laparoscopic cystectomy with hydrodissection with normal saline plus vasopressin. All the surgeries will be done by an experienced surgeon. In the case group, 3 milliliter (0.3 units) diluted vasopressin (200 folds) will be injected to the border of cyst wall and ovarian healthy tissue for hydrodissection. Ovarian reserve will be measured by sonography to assess antral follicle count and serum follicular stimulating hormone before and 2 regular menstrual cycles after surgery in the early proliferative phase of menstrual cycle (days 3-6). During operation, if needed electrocoagulation bipolar (35 watt) will be used to achieve hemostasis. The film of surgery will be reviewed for checking the operation time, and the number of electrocoagulation used. All patients will be assessed bleeding by checking the hemoglobin before and 72 hours after the surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012512262N1**

Registration date: **2013-04-05, 1392/01/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-05, 1392/01/16

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-05-03, 1391/02/14

Expected recruitment end date

2013-04-20, 1392/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of Vasopressin injection on decreasing time of surgery and need to electrocoagulation for hemostasis during laparoscopic cystectomy of patients referred to Zanan Hospital because of endometriomas

Public title

The effect of Vasopressin on decreasing time of surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:female;18-35 years old; a unilateral ovarian endometrioma; regular menstrual cycles
exclusion criteria : female younger than 18;female older than 35;bilateral ovarian cyst;irregular menstrual cycles; prior ovarian surgery ;usage of oral contraceptive pills before surgery;diagnosis of malignancy

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

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**

Ethics committee of Tehran University of Medical Science

Street address

Tehran University of Medical Science, Poursina Ave, Keshavarz Blvd, Tehran, Iran

City

Tehran

Postal code**Approval date**

2013-01-13, 1391/10/24

Ethics committee reference number

91/130/2628/3

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**

operation time

Timepoint

from the begining of dissection of the cyst wall till the complete dissection

Method of measurement

seconds

2**Description**

electrocagulation to achieve hemostasis

Timepoint

during operation

Method of measurement

counting the number of it in the film of surgery

Secondary outcomes**1****Description**

ovarian reserve

Timepoint

before and 2 months after surgery

Method of measurement

antral follicules by sonography

2**Description**

bleeding rate

Timepoint

before and 72 houres later than surgery

Method of measurement

hemoglobin (mg/dl)

Intervention groups**1****Description**

In case group,before the dissection of cyst wall ,3 milliliters containing 0.3 units diluted vasopressin of an ampule of vasopressin named (Hypress) which contains 20 units of vasopressin and diluted 200 times by adding 200 milliliters normal saline will be injected in the space between cyst wall and ovary by the specific needle,the injection will be in one place near the grater vessels. Then, 50-70 mililiters normal saline will be injected in multiple points . The cyst wall will be sent for pathological evaluation after stripping.Then the cyst`s

bed would be assessed for bleeding and if needed electrocoagulation would be used for hemostasis

Category

Treatment - Surgery

2**Description**

In control group,before the dissection of cyst wall , 50-70 milliliters of normal saline will be injected in multiple points in the space between cyst wall and ovary by the specific needle,the. Then, The cyst wall will be sent for pathological evaluation after stripping.Then the cyst`s bed would be assessed for bleeding and if needed electrocoagulation would be used for hemostasis

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

The Great Women Hospital

Full name of responsible person

Dr Mina Akrami

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Science,

Full name of responsible person

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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,

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**

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Web page address**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