

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation the effect of vasopressin injection during operation of endometrioma on the ovarian reserve in reproductive age endometriotic women.

Protocol summary

Study aim

Determining the effect of local vasopressin injection during laparoscopic cystectomy in patients with endometrioma on ovarian reserve

Design

This non blinded ,parallel, randomized clinical trial (phase II) with control group is performed on 100 women aged 18-45 years . For randomization we used the random function of Excel software.

Settings and conduct

All surgeries are performed by a surgeon at a private referral hospital(Dena Hospital, Shiraz, Iran). In the intervention group, 5 cc of vasopressin solution (10 units in 20 cc of normal saline) is injected into the mesoovarium and then cystectomy for ovarian endometriosis is performed. Then we examine and compare the difference of ovarian reserve in each group using SPSS 18.0 software with an error coefficient of 5%.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Age 18-45 Unilateral endometrioma
Exclusion criteria:Bilateral endometrioma Menopausal women Any contraindication for surgery

Intervention groups

In the intervention group, 5 cc of vasopressin solution (10 units in 20 cc of normal saline) is injected into the ovary and in the control group, no intervention is performed.

Main outcome variables

In both groups, an anti mullerian hormone (AMH) as an ovarian reserve test is performed one , three , six and nine months after operation. The number of cauterization points required for homeostasis and bleeding amount during procedure in both groups are compared. Then we examine and compare the difference in rate of (AMH) in each group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200925048836N1**

Registration date: **2020-10-26, 1399/08/05**

Registration timing: **retrospective**

Last update: **2020-10-26, 1399/08/05**

Update count: **0**

Registration date

2020-10-26, 1399/08/05

Registrant information

Name

Elham Askary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 2365

Email address

elliaskary_md@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-29, 1398/07/07

Expected recruitment end date

2020-09-28, 1399/07/07

Actual recruitment start date

2019-09-29, 1398/07/07

Actual recruitment end date

2020-09-28, 1399/07/07

Trial completion date

2021-03-02, 1399/12/12

Scientific title

Evaluation the effect of vasopressin injection during operation of endometrioma on the ovarian reserve in reproductive age endometriotic women.

Public title

Evaluation the effect of vasopressin in ovarian endometriosis surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-45 With unilateral endometriosis of the ovaries undergoing cystectomy

Exclusion criteria:

Bilateral endometrioma Menopausal women Any contraindication for surgery

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz Ethics Committee in Medical School Research

Street address

Zand Blvd, Faghihi hospital OB& GYN ward

City

Shiraz

Province

Fars

Postal code

07134814336

Approval date

2017-06-14, 1396/03/24

Ethics committee reference number

IR.SUMS.MED.REC.1396.59

Health conditions studied

1

Description of health condition studied

Treatment of ovarian endometrioma

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

Ovarian reserve

Timepoint

0,3,6 Months post operation

Method of measurement

Blood sampling

Secondary outcomes

1

Description

The number of cauterization points needed for homeostasis

Timepoint

At time of operation

Method of measurement

The number of points that are catheterized by a bipolar Bissinger Medizintechnik device to perform homeostasis during a cystectomy is counted and recorded.

2

Description

The amount of bleeding (milliliter) in both groups were recorded.

Timepoint

At time of operation

Method of measurement

Amount of bleeding (milliliter) is measured according to suction device measuring.

Intervention groups

1

Description

Intervention group: in the intervention group, 5 cc of vasopressin solution(Hay press, Exir Pharmaceutical company, Iran) (10 milli intensive units in 20 cc of normal saline) is injected into the avascular part of meso ovarium and then cystectomy is performed by an expert surgone with laparoscopic methods,the point of bleeding coagulated with bipolar Bissinger Medizintechnik device

and amount of bleeding is recorded according to suction device content /milliliter, then the ovarian wall is sutured

Category

Treatment - Surgery

2

Description

Control group: In the control group, without injection of vasopressin, ovarian cystectomy is performed by a skilled surgeon with laparoscopic method . Number of ovarian cauterization points that is performed with Bissinger Medizintechnik bipolar device for homeostasis and the amount of bleeding during cyst removal is measured in milliliters that are collected in the suction device during surgery, then ovarian wall suturing is performed

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Referral Private Dena Hospital

Full name of responsible person

Saeed Alborzi

Street address

Faghihi Hospital Office of Obstetrics and Gynecology

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbass Rezaeean

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Saeed Alborzi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Assistant professor

Latest degree

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Using vasopressine causes less bleeding and therefore does not reduce ovarian reserve after surgery

When the data will become available and for how long

Until the publication of the article

To whom data/document is available

Main and corresponding authors

Under which criteria data/document could be used

With respect to inclusion and exclusion criteria

From where data/document is obtainable

Main author

What processes are involved for a request to access data/document

Collected by the first author and evaluated by the documentary team and converted into statistical data

Comments