Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of hydrodissection with and without vasopressin on antimullerian hormone (AMH) in comparison with the usual method in laparoscopic endometrioma surgery: a double-blind clinical trial

Protocol summary

Study aim

Evaluation of the effect of hydrodissection with and without vasopressin on AMH (Anti-Müllerian hormone) in comparison with the usual method in laparoscopic endometrioma surgery: a double-blind clinical trial

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on all patients. Excel software rand function was used for randomization.

Settings and conduct

The study is double-blind. Will be performed at the Endometriosis Research Center Hazrat Rasool Akram Hospital of Iran University of Medical Sciences.In group one, laparoscopic cystectomy will be performed in a simple and usual way, in group two, cystectomy will be performed by hydrodissection method and in group 3, hydrodissection method will be performed with vasopressin.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Women are 18 to 35 years old at the reproductive age. With endometrioma ovarian cysts less than 10 cm. - Has unilateral ovarian cysts with a diameter of 4 to 10 cm that are confirmed by ultrasound Have a body mass index between 19 and 30. Have not received hormonal drugs, especially GnRH agonists, in the last 3 months. Exclusion criteria Patient with ovarian cancer Breastfeeding period

Intervention groups

In group one, laparoscopic cystectomy will be performed in a simple and usual way, in group two, cystectomy will be performed by hydrodissection method and in group 3, hydrodissection method will be performed with vasopressin.

Main outcome variables

Hemoglobin (Hb) levels the day after surgery and serum Anti-Müllerian hormone (AMH) levels 3 months after surgery will be measured and compared in all three groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150817023666N13**
Registration date: **2021-04-20, 1400/01/31**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-20, 1400/01/31**
Update count: **0**

Registration date

2021-04-20, 1400/01/31

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of hydrodissection with and without vasopressin on antimullerian hormone (AMH) in comparison with the usual method in laparoscopic endometrioma surgery: a double-blind clinical trial

Public title

The effect of hydrodissection on antimullerian hormone (AMH) in laparoscopic endometrioma surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women of childbearing age are 18 to 35 years old. With endometrioma ovarian cysts less than 10 cm. Has unilateral ovarian cysts with a diameter of 4 to 10 cm that are confirmed by ultrasound. Have a body mass index between 19 and 30. Have not received hormonal drugs, especially GnRH agonists, in the last 3 months.

Exclusion criteria:

Patients have unilateral ovarian cysts 4 -10 cm in diameter, which are confirmed by ultrasound sonography.

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation in this study is limited to intervention and control groups using randomization. Random allocation law is the simplest and most limited method of randomization. This method represents a large block for the total sample size. For this purpose, the researchers first determine the total sample size and then randomly divide a set of them into groups A, B, C. For example, in this study with a sample size of 15 balls, 5 balls for intervention group A and 5 balls for intervention group B, and 5 balls for the control group (C) are placed inside a lottery bowl and then the balls are randomly removed from the container and removed. This method is used for two- or multi-group experiments.

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome assessor and data analyst will not know how the groups are assigned. But because patients' consent must be obtained, the patient knows in which group. For this purpose, before random allocation, a complete explanation of the interventions is given and the patient is told that they will be randomly placed in one of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University Of Medical Sciences

Street address

Sattar Khan - Hazrat Rasool Akram Hospital

City

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Approval date

2020-10-21, 1399/07/30

Ethics committee reference number

IR.IUMS.REC.1399.684

Health conditions studied

1

Description of health condition studied

Women with endometrioma ovarian cysts

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Antimullerian Hormone changes in patients

Timepoint

Mean levels of Antimullerian Hormone in all patients before and after laparoscopic cystectomy

Method of measurement

Questionnaire and patient file

2

Description

Hemoglobin changes in patients

Timepoint

Mean levels of hemoglobin in all patients before and after laparoscopic cystectomy

Method of measurement

Questionnaire and patient file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Laparoscopic cystectomy for ovarian cyst surgery is performed by hydro dissection (50-70 ml of normal saline) in which hydrodissection is injected in several points of the cyst wall. Then the cyst wall is removed and for pathology The cyst bed is then checked for bleeding and, if necessary, an electrocautery is used for homeostasis.

Category

Treatment - Drugs

2

Description

Intervention group 2: Laparoscopic cystectomy for ovarian cyst surgery by hydro dissection; Hydrodissection method with vasopressin (Durvana company) in the intervention group, before starting to remove the wall of the cyst 3 ml, contains 0.3 units of an ampoule called vasopressin (Hypress) which contains 20 units and is diluted 200 times in 200 ml of normal saline solution It is inserted into the space between the walls of the ovarian cyst using a special needle, injected at one point of the cyst near the large vessels, followed by 50-70 ml of normal saline is injected at several points. The cyst wall is then removed and sent for pathology. The cyst bed is then checked for bleeding and, if necessary, an electrocautery is used for homeostasis.

Category

Treatment - Drugs

3

Description

Control group: Laparoscopic cystectomy for ovarian cyst surgery is performed in a simple and common way. It is a surgical procedure in which a light vision device (laparoscope) is inserted into the lower abdomen through a small incision, usually made under the umbilicus.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Dr Abolfazl Mehdizadeh Kashi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr Abolfazl Mehdizadeh Kashi

Position

professor

Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Part of data like the main outcome or the same will be shared
When the data will become available and for how long
Access after 6 months after publication
To whom data/document is available
Data will be available for all researchers
Under which criteria data/document could be used
It can be used for further research and improvement of surgery. Surgeons and gynecologists can use this data.
From where data/document is obtainable
For receiving data please be contacted with mehdizadeh.a@iums.ac.ir
What processes are involved for a request to access data/document
limitless
Comments