

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Evalution of tranexamic acid injection effect at laparoscopic cystectomy on AMH level in endometrioma patient

Protocol summary

Antimullerian Hormone Level, Treatment Procedure, History of infertility, Infertility Duration

Study aim

The effect of tranexamic acid injection in laparoscopic cystectomy on antimullerian hormone levels in patients with endometrioma

Design

After induction of anesthesia in group B patients at the rate of 10 mg / kg body weight of the patient, tranexamic acid with 100 ml of 0.9% sodium chloride serum is infused half an hour before the start of surgery. During the operation, minimal interventions (including sutures or the use of catheters) are performed to maintain homeostasis to prevent ovarian reserve depletion. Cystectomy is then performed routinely. Surgery is performed by same surgeon. In group A, only 100 ml of 0.9% sodium chloride serum is infused without tranexamic acid, and then a cystectomy is performed by the same surgeon. The relevant questionnaire is inserted and finally examined using statistical methods.

Settings and conduct

Patients with endometrioma cysts 4 to 10 cm who are candidates for laparoscopy and cyst resection and are in the age range of 18 to 40 years and refer to the laparoscopic clinic of Ali ebne Abitaleb Hospital in Zahedan and have the inclusion criteria .

Participants/Inclusion and exclusion criteria

Patients with endometrioma cysts 4 to 10 cm who are candidates for laparoscopy and cyst resection and are in the age range of 18 to 40 years and refer to the laparoscopic clinic of Ali ebne Abitaleb Hospital .

Intervention groups

Patients with symptoms of dysmenorrhea, pelvic pain, dyspareunia, or infertility who have a 4 to 10 cm unilateral endometrium cyst on ultrasound and are candidates for laparoscopic surgery are included in the study. Patients are randomly assigned to two groups of routine cystectomy without tranexamic acid (A) injection and the group with tranexamic acid (B) injection and then cystectomy.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201208049652N1**

Registration date: **2021-02-15, 1399/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-15, 1399/11/27**

Update count: **0**

Registration date

2021-02-15, 1399/11/27

Registrant information

Name

Hamideh Hanafi Bojd

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3344 2384

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h.hanafi@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of tranexamic acid injection effect at laparoscopic cystectomy on AMH level in endometrioma patient

Public title

Tranexamic acid injection effect at laparoscopic cystectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients between 18-40 years old with regular menstruation and endometrioma Unilateral endometrioma cyst with 4-10 cm

Exclusion criteria:

History of previous ovarian surgery and pelvic adhesion
History of previous endocrinology diseases (Diabetes, Hyperprolactinoma) PID History of previous chemotherapy History of previous PTE Cyst other than endometrioma intraoperative Cigarette Smoking , OCP consumption Severe Renal Disease Tranexamic acid injection contraindication

Age

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

Gender

Female

Phase

0

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

On the 30 small cards, the letter A is written and on the other 30 cards, the letter B is written. In the previous section, it was explained how the execution protocol is. Gives the operating room technician to select one of the cards and place the patient in one of the groups according to the same protocol and indicate the group on the patient information questionnaire. In this process, the surgeon and the researcher are blind to the group in which the patient is located. In other words, he becomes blind on both sides.

Blinding (investigator's opinion)

Double blinded

Blinding description

On the 30 small cards, the letter A is written and on the other 30 cards, the letter B is written. In the previous section, it was explained how the execution protocol is. Gives the operating room technician to select one of the cards and place the patient in one of the groups according to the same protocol and indicate the group on the patient information questionnaire. In this process, the surgeon and the researcher are blind to the group in

which the patient is located. In other words, he becomes blind on both sides.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Zahedan University of Medical Sciences Ethic Committee

Street address

Pardis of Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-07-21, 1398/04/30

Ethics committee reference number

IR.ZAUMS.REC.1398.268

Health conditions studied**1****Description of health condition studied**

Endometriosis , Laparoscopy

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes**1****Description**

Antimullerian Hormone Level

Timepoint

3 , 6 month

Method of measurement

ng/ml

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

Antimullerian Hormone Level

Timepoint

3 , 6 month

Method of measurement

ng/ml

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

Intervention group: Cystectomy with tranexamic acid injection. Patients are randomly assigned to two groups of routine cystectomy without injection of tranexamic acid (A) and the group with injection of tranexamic acid (B) and then cystectomy. After induction of anesthesia in group B patients at a rate of 10 mg / kg , body weight of the drug tranexamic acid is infused with 100 ml of 0.9% sodium chloride serum half an hour before surgery. During surgery, minimal interventions (such as sutures or the use of a catheter) are performed to maintain homeostasis to prevent a reduction in ovarian reserve. Cystectomy is then performed routinely. Surgery is performed by a surgeon

Category

Treatment - Drugs

2**Description**

Control group: (Group A) : Cystectomy without tranexamic acid injection. In group A (control), only 100 ml of 0.9% sodium chloride serum is infused without tranexamic acid and then cystectomy is performed by the same surgeon.

Category

Treatment - Drugs

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

Ali Ebne Abitaleb Hospital

Full name of responsible person

OR Cheif

Street address

Khalij Fars Blvd , Salamat Blvd

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Web page address<http://alihos.zaums.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

Research Deputy

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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

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Maryam Razavi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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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

After determining the results of the article printing program

When the data will become available and for how long

It is not clear.

To whom data/document is available

People allowed by Zahedan University of Medical Sciences .

Under which criteria data/document could be used

People allowed by Zahedan University of Medical Sciences .

From where data/document is obtainable

People allowed by Zahedan University of Medical Sciences .

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

Correspondence with Zahedan University of Medical Sciences.

Comments