Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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

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

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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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
Evalution 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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http://alihos.zaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
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Zahedan University of Medical Sciences
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public@zaums.ac.ir
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