Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the efficacy of vasopressin injection for adhisionolysis of bowel DIE (deep infilterating endometriosis)in laparoscopic surgery for severe endometriosis

Protocol summary

Study aim
Comparison the efficacy of vasopressin injection for adhisionolysis of bowel DIE in laparoscopic surgery for severe endometriosis

Design
This is a double blind phase 3 randomized clinical trial which patients and physician are blinded regarding groups. Vasopressin (case group) or saline(control group)will be injected in posterior of uterus ,then ease of adhisionolysis, Bleeding,and surgical complications will be recorded

Settings and conduct
All patients with endometriosis of bowel randomly will be allocated in case(vasopressin)or control (normal salin)group for injection to the posterior uterine wall during laparoscopy in Yas hospital, then the ease of adhisionolysis, bleeding,and complications will be recorded.

Participants/Inclusion and exclusion criteria
Age 20-50 Stage 3-4 endometriosis according to ASRM Severe adhesion in pelvis Exclusion criteria Hypersensitivity to vasopressin Endocrine disease

Intervention groups
Intervention group: In intervention group 50 patients will allocated and diluted injection vasopressin in 200 cc normal salin will injected in low posterior wall of uterus. Bleeding, ease of adhesion dissection, surgical complications will be recorded.

Main outcome variables
Time of surgery,Bleeding,bowel injury, ease of dissection will be evaluated after surgery by questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091012002576N27**
Registration date: **2023-01-27, 1401/11/07**
Registration timing: **prospective**

Last update: **2023-01-27, 1401/11/07**
Update count: **0**

Registration date
2023-01-27, 1401/11/07

Registrant information

Name
Fatemeh Davari Tanha

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 8831 3955

Email address
fdavaritanha@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-30, 1401/11/10

Expected recruitment end date
2023-08-01, 1402/05/10

Actual recruitment start date
2023-01-30, 1401/11/10

Actual recruitment end date
2023-08-01, 1402/05/10

Trial completion date
2023-08-01, 1402/05/10

Scientific title
Comparison the efficacy of vasopressin injection for adhisionolysis of bowel DIE (deep infilterating

endometriosis)in laparoscopic surgery for severe endometriosis

Public title
Efficacy of vasopressin for adhisionolysis of bowel DIE in laparoscopy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 20-50 Stage 3-4 endometriosis according to ASRM Severe adhesion in pelvis
Exclusion criteria:
Hypersensitivity to vasopressin Endocrine disease
Age
From **20 years** old to **50 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
After randomization 100 patients randomly will assigned in intervention group who wii received diluted injection vasopressin in 200 cc normal salin in low posterior wall of uterus, or control group who received injection of normal salin in the site of adhesion. Bleeding, ease of adhesion dissection, surgical complications will be recorded. 50 letters A and 50 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patients. In addition, interventions A (case group) or B (control group) are determined by a lot.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double blind intervention which patients and physician are blinded regarding groups. Patients and care providers are blinded regarding the case and control groups with using saline that is the same as vasopressin regarding the appearance.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Tehran University of medical sciences
Street address
Deputy of research, sixth floor of central building of Tehran University of medical sciences, Ghods Avenue, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1597815978
Approval date
2023-01-23, 1401/11/03
Ethics committee reference number
IR.TUMS.MEdICINE.REC.1401.703

Health conditions studied

1

Description of health condition studied
Severe endometriosis
ICD-10 code
ICD-10 code description
N97.8

Primary outcomes

1

Description
Time of surgery,Bleeding,bowel injury, ease of dissection
Timepoint
After surgery
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Dysmenorrhoea, dysparunia,chemical pregnancy, clinical pregnancy
Timepoint
3-6 months after surgery
Method of measurement
Questionnaire,bhcg test

Intervention groups

1

Description

Intervention group: In intervention group 50 patients will allocated and diluted injection vasopressin in 200 cc normal salin will injected in low posterior wall of uterus. Bleeding, ease of adhesion dissection, surgical complications will be recorded.

Category

Treatment - Surgery

2

Description

Control group: 5o patients randomly will assigned in control group who received injection of normal salin in the site of adhesion. Bleeding, ease of adhesion dissection, surgical complications will be recorded.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Yes hospital

Full name of responsible person

Fatemeh Davari Tanha

Street address

Yas hospital, North Ostad Nejatollahi Avenue, Karim khan Zand Blvd.

City

Tehran

Province

Tehran

Postal code

1597815978

Phone

+98 21 4216 0000

Email

Fatedavtanha@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Davari Tanha

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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 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

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Davari Tanha

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Yas hospital, North Ostad Nejatollahi Avenue, Karim khan Zand Blvd.

City

Tehran

Province

Tehran

Postal code

1598718311

Phone

+98 21 8831 3955

Fax

+98 21 8831 3955

Email

fdavaritanha@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

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Web page address

Person responsible for updating data

Contact
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Postal code
1598718311
Phone
+98 21 8831 3955
Fax
Email
fatedavari@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be 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
The data are available by mail
When the data will become available and for how long
SPSS data after publishing data till 3 years
To whom data/document is available
Academic Researchers
Under which criteria data/document could be used
For scientific purpose
From where data/document is obtainable
Mail to:fatedavtanha @gmail.com
What processes are involved for a request to access data/document
Two weeks after email the data will be available.
Comments