

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

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

Protocol summary

Study aim

Comparison the efficacy of vasopressin injection for adhesionolysis 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 adhesionolysis, 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 saline) group for injection to the posterior uterine wall during laparoscopy in Yas hospital, then the ease of adhesionolysis, 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 be allocated and diluted injection vasopressin in 200 cc normal saline will be 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 adhesionolysis of bowel DIE (deep infiltrating

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: 50 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

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

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Fatedavtanha@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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

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

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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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Davari Tanha

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