Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparison of intra-myomic injection of oxytocin and intramural vasopressin in reducing laparoscopic myomectomy bleeding in women with myoma

Protocol summary

Study aim

Comparison of intra-myomic injection of oxytocin and intramural vasopressin in reducing laparoscopic myomectomy bleeding in women referred to Rasool Akram Hospital from 2021-2022

Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients. To randomize the balls, the balls are taken out of the container without replacement and the created sequence is recorded.

Settings and conduct

The study site is the operating room of the gynecology ward of Rasoul Akram Hospital in Tehran, which is performed on all patients undergoing laparoscopic myomectomy. This is a double-blind trial in which the participant, the data collector, and the data analyzer are blind to the type of drug. One participant receives oxytocin and the other vasopressin, and the patient is told that he or she will receive one of these two drugs, and data is sent to the analyzer named A and B, without knowing their nature.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20 to 45 years; Symptomatic uterine fibroids candidate for laparoscopic surgery, non-response to drug therapy. Non-inclusion criteria: Underlying diseases related to blood factors; Pregnancy; Women who are candidates for hysterectomy; History of adverse reaction or allergy to vasopressin; active cardiovascular or pulmonary disease indicating difficulty using vasopressin

Intervention groups

Intervention group: Vasopressin is diluted with a concentration of 0.2 U / ml and injected intramyometrialy (between myoma and uterus) and subcapsulary. Control group: Prophylaxis oxytocin is diluted and injected intramyometrialy (between the myoma and the uterus) and subcapsulary. For this purpose, a 10 mg ampoule is diluted with 300 cc of normal saline and 100 cc is injected.

Main outcome variables

Amount of blood loss during surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150817023666N15**
Registration date: **2022-07-03, 1401/04/12**
Registration timing: **prospective**

Last update: **2022-07-03, 1401/04/12**
Update count: **0**

Registration date

2022-07-03, 1401/04/12

Registrant information

Name

Abolfazl Mehdizadeh kashi

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 216651500

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mehdizadeh.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-21, 1401/04/30

Expected recruitment end date

2025-02-18, 1403/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of intra-myomic injection of oxytocin and intramural vasopressin in reducing laparoscopic myomectomy bleeding in women with myoma

Public title
The effect of oxytocin and vasopressin in reducing laparoscopic myomectomy bleeding in women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 20 to 45 years Symptomatic uterine fibroids candidate for laparoscopic surgery No response to drug treatment

Exclusion criteria:
Underlying diseases related to blood factors Pregnancy Women who are candidates for hysterectomy People for whom anesthesia is harmful A history of an adverse reaction or allergy to vasopressin, and an active cardiovascular or pulmonary disease that indicates a problem with vasopressin use. Long QT interval Leiomyoma located in the area of the uterus that connects to the arteries or ligaments of the uterus or cervix and is difficult to remove without hysterectomy.

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, with a sample size of 60 people, 30 balls for intervention group A and 30 balls for intervention group B were placed in a lottery container and then the balls were randomly pulled out from the container without replacement.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blind study. The participant, the data collector, and the data analyzer are blind to the type of drug. One participant receives oxytocin and the other vasopressin, and the patient is told that he or she will receive one of these two drugs, and data is sent to the analyzer named A and B, without knowing their nature.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Hazrat Rasoul Akram Hospital; Niayesh St.; Sattar Khan St.; Tehran.

City
Tehran

Province
Tehran

Postal code
1445613131

Approval date
2022-06-20, 1401/03/30

Ethics committee reference number
IR.IUMS.REC.1401.273

Health conditions studied

1

Description of health condition studied
Bleeding during surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Bleeding during surgery

Timepoint
The volume of suctioned blood is measured during the operation, after surgery and 12 hours after the operation.

Method of measurement
Measurement of blood hemoglobin

Secondary outcomes

1

Description
Fever

Timepoint

Before and after surgery and 12 hours after surgery

Method of measurement

Patient's file (document)

2

Description

Infection

Timepoint

Before and after surgery and 12 hours after surgery

Method of measurement

Patient's file (document)

3

Description

Duration of surgery

Timepoint

Before and after surgery and 12 hours after surgery

Method of measurement

Patient's file (document)

4

Description

Duration of hospitalization

Timepoint

Before and after surgery and 12 hours after surgery

Method of measurement

Patient's file (document)

5

Description

Postoperative side effects such as allergies

Timepoint

Before and after surgery and 12 hours after surgery

Method of measurement

Patient's file (document)

6

Description

Cardiovascular disorders

Timepoint

Before and after surgery and 12 hours after surgery

Method of measurement

Patient's file (document)

7

Description

Pulmonary edema

Timepoint

Before and after surgery and 12 hours after surgery

Method of measurement

Patient's file (document)

Intervention groups

1

Description

Control group: Prophylaxis oxytocin is diluted and injected intramyometrialy (between the myoma and the uterus) and subcapsulary. For this purpose, a 10 mg ampoule is diluted with 300 cc of normal saline and 100 cc is injected.

Category

Treatment - Drugs

2

Description

Intervention group: Vasopressin is diluted with a concentration of 0.2 U / ml and totally 4-6 units is injected intramyometrialy (between myoma and uterus) and subcapsulary.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Abolfazl Mehdizadeh Kashi

Street address

Hazrat Rasoul Akram Hospital; Niayesh St.; Sattar Khan St.; Tehran.

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mehdizadeh.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Hossein Keyvani-Vice President for Research of Iran University of Medical Sciences

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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
Abolfazl Mehdizadeh Kashi
Position
Professor of Laparoscopic Surgery
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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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
Not applicable
Title and more details about the data/document
Part of data like the main outcome or some others could 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

Send a letter to mehdizadeh.a@iums.ac.ir to provide them with the documents.

Comments