

# 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 Rasool 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 intramyometrially (between myoma and uterus) and subcapsulary. Control group: Prophylaxis oxytocin is diluted and injected intramyometrially (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

##### Email address

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 intramyometrial (between the myoma and the uterus) and subcapsular. 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 intramyometrial (between myoma and uterus) and subcapsular.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Rasool Akram Hospital

**Full name of responsible person**

Abolfazi Mehdizadeh Kashi

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**Email**

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****Contact****Name of organization / entity**

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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**