

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Assessment of intravenous sedation effect on surgery pain in hysteroscopic polypectomy compared with paracervical block

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Summary

The aim of this study is the assessment of intravenous sedation effect on surgery pain in hysteroscopic polypectomy compared with paracervical block. This is a randomized, not blinded, single-center study that is performed in Arash hospital, Tehran, Iran. Among women referred to Arash hospital laparoscopy clinic who have polyp less than 3 centimeter diameter based on ultrasonography and, are the candidate of hysteroscopic polypectomy are enrolled in the study. Inclusion criteria are patients aged between 18- 50 years old without history of cardiopulmonary diseases. Exclusion criteria are Lidocaine sensitivity and excess anxiety. After receiving informed consent, all patients are randomly divided into 3 groups of 28 members including: intravenous sedation; paracervical block and general anesthesia in intravenous sedation 1 micro grams/kg fentanyl and 0.1 mg/kg Midazolam is injected. Then 3 micro grams / kg Propofol is infused. In paracervical block 10 cc of 2% Lidocaine is injected in 4 and 8 o'clock of cervicovaginal mucous in Lithotomy position. In general anesthesia group, 1 micro grams/kg fentanyl and 0.1 mg/kg Midazolam is injected and consequently 100 micro grams / kg Propofol is infused. Then the surgery starts. In general anesthesia group, the amount of pain is asked in recovery room and 3 hours after surgery. In two other groups, the amount of pain is asked during inserting hysteroscope, polypectomy, curretaging, recover room and 3 hours after surgery. Pain is recorded based on visual analogue scale. The amount of pain, operation time and polyp 6 months recurrence is compared in all groups.

Last update:

Update count: **0**

#### Registration date

2016-04-28, 1395/02/09

#### Registrant information

##### Name

Maryam Razavi

##### Name of organization / entity

Tehran university of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7771 9922

##### Email address

mravazi@razi.tums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2016-04-18, 1395/01/30

#### Expected recruitment end date

2016-05-30, 1395/03/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

#### Scientific title

Assessment of intravenous sedation effect on surgery pain in hysteroscopic polypectomy compared with paracervical block

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2016031426855N3**

Registration date: **2016-04-28, 1395/02/09**

#### Public title

Assessment of intravenous sedation effect on pain of surgical removing polyps compared with local anesthesia

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: patients aged between 18- 50 years old with polyps less than 3 cm; no history of cardiopulmonary diseases. Exclusion criteria: Lidocaine sensitivity; excess anxiety.

### **Age**

From **18 years** old to **50 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **84**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Tehran University of Medical Science

##### **Street address**

Qods Street, Keshavarz Boulevard

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2016-03-14, 1394/12/24

#### **Ethics committee reference number**

IR.TUMS.REC.1394.2225

## **Health conditions studied**

### 1

#### **Description of health condition studied**

polypectomy

#### **ICD-10 code**

n84

## **ICD-10 code description**

Polyp of corpus uteri

## **Primary outcomes**

### 1

#### **Description**

The pain of surgery

#### **Timepoint**

During and 3 hours after surgery ( in general anesthetic group: only the pain of 3 hours after surgery)

#### **Method of measurement**

Visual analogue scale

## **Secondary outcomes**

### 1

#### **Description**

Post operative recurrence of polyp

#### **Timepoint**

6 months after surgery

#### **Method of measurement**

Ultrasound

### 2

#### **Description**

Duration of operation

#### **Timepoint**

From anesthesia induction to discharge of recovery room

#### **Method of measurement**

Hour

### 3

#### **Description**

Complications of analgesia method

#### **Timepoint**

During analgesia, during surgery and 3 hours after surgery

#### **Method of measurement**

Check list

## **Intervention groups**

### 1

#### **Description**

General anesthesia: 1 micro grams/ kg Fentanyl and 0.1 mg/kg Midazolam is injected and consequently 100 micro grams / kg Propofol is infused. Then the surgery starts.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

In intravenous sedation: 1 micro grams/kg fentanyl and 0.1 mg/kg Midazolam is injected. Then 3 micro grams / kg Propofol is infused.

**Category**

Treatment - Drugs

3**Description**

In paracervical block: 10 cc of 2% Lidocaine is injected in 4 and 8 o'clock of cervicovaginal mucous in Lithotomy position.

**Category**

Treatment - Drugs

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Arash Women's Hospital

**Full name of responsible person**

Maryam Razavi

**Street address**

Arash Women 's Hospital, Rashid Ave, Resalat Highway

**City**

Tehran

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences , Deputy of Research

**Full name of responsible person**

Dr. Masoud Younesian

**Street address**

Qods St, Keshavarz Blvd

**City**

Tehran

**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 , Deputy of Research

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Arash Women's Hospital, Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Razavi

**Position**

Women specialist

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arash Women 's Hospital, Tehran University of Medical Sciences, Tehran, Iran

**Full name of responsible person**

Zahra Asgari

**Position**

Associated professor

**Other areas of specialty/work****Street address**

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**Full name of responsible person**

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**Position**

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mrzavi@razi.tums.ac.ir  
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*