

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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

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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

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031426855N3**

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

Scientific title

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

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 centers1**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

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences , Deputy of Research

Full name of responsible person

Dr. Masoud Younesian

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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 , 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

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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