

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparative evaluation of effect of General anesthesia, Spinal anesthesia and Paracervical block on pain, nausea, vomiting and analgesic requirements in diagnostic Hysteroscopy.

#### Protocol summary

##### Study aim

Comparison of effect of General anesthesia, Spinal anesthesia and Paracervical block on pain, nausea, vomiting and analgesic requirements in diagnostic Hysteroscopy.

##### Design

This phase 2 clinical trial with parallel groups and without control group will be performed on 66 patients aged 18 to 45 years who are candidates for diagnostic hysteroscopy.

##### Settings and conduct

In general anesthesia group, 0.02mg/kg midazolam, 1ug/kg Fentanyl and 2mg/kg of propofol are injected intravenously and the suitable LMA is placed. In spinal anesthesia group, after spinal anesthesia, 0.02 mg/kg of midazolam and 1ug/kg fentanyl are injected intravenously for sedation. In paracervical group, first 0.02mg/kg midazolam and 1ug/kg fentanyl injected intravenously and after 3-5 minutes, 10 ml lidocaine 2% will inject by a spinal needle no.25 at 3, 9, 5 and 7 hours in cervico vaginal junction. The patient is then subjected to hysteroscopy with a rigid hysteroscope and vital signs, nausea, analgesic consumption and patient satisfaction at different times are measured.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 to 45 years; ASA class 1&2; Candidate for hysteroscopic surgery; Do not use analgesics for 24 hours before surgery; Absence of contraindications to spinal anesthesia and general anesthesia. Exclusion criteria: History of allergies to local anesthetics and propofol; Electrolyte disturbances; History of previous hysteroscopic surgery; History of nausea and vomiting following previous anesthesia or history of motion sickness; Lack of patient cooperation after initial interventions and coagulation disorders.

##### Intervention groups

In this study, patients in three groups of general

anesthesia, spinal anesthesia and paracervical block are evaluated for vital signs, nausea, analgesic consumption and satisfaction.

##### Main outcome variables

The VAS of pain and analgesic requirement in recovery.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120915010841N26**

Registration date: **2021-11-07, 1400/08/16**

Registration timing: **prospective**

Last update: **2021-11-07, 1400/08/16**

Update count: **0**

##### Registration date

2021-11-07, 1400/08/16

##### Registrant information

##### Name

Nahid Manouchehrian

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1827 7012

##### Email address

manouchehrian@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-05, 1400/09/14

##### Expected recruitment end date

2022-03-05, 1400/12/14

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative evaluation of effect of General anesthesia, Spinal anesthesia and Paracervical block on pain, nausea, vomiting and analgesic requirements in diagnostic Hysteroscopy.

**Public title**

Comparison of three anesthesia methods in hysteroscopic surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients 18 to 45 years ASA class1&2 Candidate for diagnostic hysteroscopic surgery Satisfaction to participate in the study Do not use analgesics for 24 hours before surgery Absence of contraindications to spinal anesthesia and general anesthesia

**Exclusion criteria:**

History of allergies to local anesthetics and propofol Cardiac, respiratory, renal and liver diseases Candidate patients for myomectomy or polypectomy with resectoscope Electrolyte disturbances (sodium, potassium and calcium Uterine prolapse History of previous cervical or hysteroscopic surgery History of nausea and vomiting following previous anesthesia or history of motion sickness Lack of patient cooperation after initial interventions Coagulation disorders

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **66**

**Randomization (investigator's opinion)**

Not 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 Hamadan University of Medical Sciences

**Street address**

Mahdieh Street

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838678

**Approval date**

2021-01-16, 1399/10/27

**Ethics committee reference number**

IR.UMSHA.REC.1399.875

## Health conditions studied

1

**Description of health condition studied**

Hysteroscopic surgery under general anesthesia, spinal anesthesia or para cervical block

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

1

**Description**

Post operative pain

**Timepoint**

After surgery in recovery

**Method of measurement**

Using visual analog scale (VAS)

2

**Description**

Analgesic requirement

**Timepoint**

After surgery in recovery

**Method of measurement**

Based on the amount of analgesia requested by the patient

## Secondary outcomes

1

**Description**

Systolic and Diastolic Blood Pressure

**Timepoint**

Before and after general or regional anesthesia, insertion of Spacolom and Tenacolom, dilation of cervix, insertion

of hysteroscope, biopsy and extraction of hysteroscope

#### **Method of measurement**

Non-invasive automatic barometric device

### **2**

#### **Description**

Nausea & vomiting

#### **Timepoint**

After surgery in recovery

#### **Method of measurement**

Observation

### **3**

#### **Description**

Heart Rate

#### **Timepoint**

Before and after general or regional anesthesia, insertion of Spacolom and Tenacolom, dilation of cervix, insertion of hysteroscope, biopsy and extraction of hysteroscope

#### **Method of measurement**

Pulseoximetry

### **4**

#### **Description**

Shivering

#### **Timepoint**

After surgery in recovery

#### **Method of measurement**

Observation

### **5**

#### **Description**

Satisfaction rate

#### **Timepoint**

Before discharge from recovery

#### **Method of measurement**

Asking the patient

## **Intervention groups**

### **1**

#### **Description**

Intervention group1: In all patients after entering the operating room, using a 18 intravenous lines, after receiving 5 ml/kg of serum Ringer, in general anesthesia group, 0.02mg/kg midazolam, 1ug /kg Fentanyl and 2mg/kg of propofol are injected intravenously and then the suitable LMA is placed (proportional to the patient's weight) and is used to maintain anesthesia from 1.2% isoflurane and 50%N2o.The patient is then subjected to hysteroscopy with a rigid hysteroscope (Storz Hysteroscope No. 7, Germany), and the uterine cavity is dilated using Glycine solution1.5% and vital signs(Saadat,162 model, non invasive monitoring, Iran), nausea, pain (VAS), analgesic consumption and patient satisfaction(%) at different times are measured.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention group 2: In all patients after entering the operating room, using a 18 intravenous lines, after receiving serum 5 ml/kg of serum Ringer, in spinal anesthesia group, the patient is placed in a sitting position and after determining the subarachnoid space in the L3-L4 or L4-L5 space, 2.5 mg of 0.5% bupivacaine is injected.Then, sensory level is examined by pinprick and in an anesthetic level of T10, the surgical procedure started and 0.02 mg/kg of midazolam and 1ug/kg fentanyl are used for sedation.The patient is then subjected to hysteroscopy with a rigid hysteroscope (Storz Hysteroscope No. 7, Germany), and the uterine cavity is dilated using Glycine solution1.5% and vital signs(Saadat,162 model, non invasive monitoring, Iran), nausea, pain (VAS), analgesic consumption and patient satisfaction(%) at different times are measured.

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

Intervention group 3: In all patients after entering the operating room, using a 18 intravenous lines, after receiving 5 ml/kg of serum Ringer, in paracervical group, first 0.02mg/kg midazolam and 1ug/kg fentanyl Injected intravenously and after 3-5 minutes, 10 ml lidocaine 2% will inject by a spinal needle no.25 at 3, 9, 5 and 7 hours in cervico vaginal junction, and after 5 minutes, the patient is evaluated for adequate anesthesia and surgery will begin. The patient is then subjected to hysteroscopy with a rigid hysteroscope (Storz Hysteroscope No. 7, Germany), and the uterine cavity is dilated using Glycine solution1.5% and vital signs(Saadat,162 model, non invasive monitoring, Iran), nausea, pain (VAS), analgesic consumption and patient satisfaction(%) at different times are measured.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Fatemieh Hospital

##### **Full name of responsible person**

Nahid Manouchehrian

##### **Street address**

Fatemieth Hospital, Pasdaran Street

##### **City**

Hamadan

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##### **Postal code**

6517789971

##### **Phone**

+98 81 3827 7012

##### **Email**

hp.fatemieh@gmail.co

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeed Bashirian

**Street address**

Mahdie Street

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vc\_research@umsha.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Nahid Manouchehrian

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

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Hamedan University of Medical Sciences

**Full name of responsible person**

Nahid Manouchehrian

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available