

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparative study of the effect of general anesthesia and low dose spinal anesthesia in hysteroscopy on postoperative pain, nausea and vomiting

Protocol summary

Study aim

Comparison of general anesthesia and low dose spinal anesthesia in hysteroscopy on postoperative pain, nausea and vomiting

Design

Study groups: A group that has undergone hysteroscopy under general anesthesia The group underwent hysteroscopic spinal anesthesia under low dose. Sample size: 88 people in two groups of 44 people Random clinical trial with two control groups Two-way blind Parallel groups Random assignment of all samples with spss software

Settings and conduct

A total of 88 hysteroscopic candidates in Shahid Beheshti Hospital in Isfahan are randomly assigned to one of the two groups of general anesthesia and low dose spinal. Postoperatively during the first 15 minutes of entry into recovery, at the time of discharge from recovery and 4 hours after surgery; The presence or absence of nausea and vomiting is assessed and their pain is assessed by the VAS criterion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. In terms of anesthesia in II and I ASA 2. Satisfaction to enter the study 3- Age between 18-60 years 4. Candidate patients for hysteroscopic surgery based on the opinion of a gynecologist Exclusion criteria: Drug use, use of antidepressants, pregnancy, heart disease, hypothyroidism and hyperthyroidism, sensitivity to anesthetic drugs, severe bleeding during surgery, severe hemodynamic disorders, allergic symptoms and acute pelvic infection The study will be out

Intervention groups

One group underwent general anesthesia and the other group underwent low-dose spinal hysteroscopy.

Main outcome variables

Distribution of relative frequency of postoperative vomiting Distribution of relative frequency of

postoperative nausea Frequency distribution of mean postoperative pain score by VAS criterion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120201008897N9**

Registration date: **2021-05-23, 1400/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-23, 1400/03/02**

Update count: **0**

Registration date

2021-05-23, 1400/03/02

Registrant information

Name

Safoura Rouholamin

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1236 7001

Email address

s_rouholamin@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of general anesthesia and low dose spinal anesthesia in hysteroscopy on postoperative pain, nausea and vomiting

Public title

Comparative study of general anesthesia and low dose spinal anesthesia in hysteroscopic patients on postoperative pain, nausea and vomiting

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate for hysteroscopy based on the opinion of a gynecologist In terms of anesthesia in II and I ASA
Consent to enter the study

Exclusion criteria:**Age**From **18 years** old to **60 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **88****Randomization (investigator's opinion)**

Randomized

Randomization description

Random assignment of all studied samples or using SPSS randomization software is done. Method: Simple randomization Unit: Individual Tools: Statistical software Layered randomization: None Hiding: All samples studied or using SPSS randomization software is done.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, only the person who collects the information and also the person who performs the statistical analysis are unaware of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan Hezar Jerib St. Isfahan University of Medical Sciences and Health Services

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-04-25, 1400/02/05

Ethics committee reference number

IR.MUI.MED.REC.1400.038

Health conditions studied**1****Description of health condition studied**

Candidates for hysteroscopy based on the opinion of a gynecologist

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain score based on Visual Analogue scale - nausea and vomiting

Timepoint

The first 15 minutes of recovery - when discharge - 4 hours after surgery

Method of measurement

Patient pain rate based on Visual analoguse scale - nausea and vomiting based on patient question (yes - no)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: People undergoing general hysteroscopy under general anesthesia

Category

Treatment - Surgery

2**Description**

Intervention group: People undergoing low-dose spinal hysteroscopy
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
shahid beheshti hospital
Full name of responsible person
safoura rouholamin
Street address
Isfahan - Ostad Motahhari Street
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 5554 0029
Email
s_rouholamin@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
safoura rouholamin
Street address
Isfahan Hezar Jerib Street
City
isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
s_rouholamin@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
safoura rouholamin
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Isfahan Hezar Jerib Street
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3663 9903
Email
s_rouholamin@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
safoura rouholamin
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Isfahan Hezar Jerib St., Isfahan University of Medical Sciences
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3663 9903
Email
s_rouholamin@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

safoura rouholamin

Position

associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Isfahan Hezar Jerib St., Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3663 9903

Email

s_rouholamin@med.mui.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No; The data will not be shared separately, but the results of their analysis will be shared in the article

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available