Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 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

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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 size
Target 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
Isfehan
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

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Sponsors / Funding sources

1

Sponsor

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Esfahan 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
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

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Person responsible for updating data

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Latest degree
Subspecialist
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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