Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of Intraoperative Dexamethasone Infusion in Mitigating Shoulder Pain and Postoperative Nausea and Vomiting Following Laparoscopic Hysterectomy

Protocol summary

Study aim
Efficacy of Intraoperative Dexamethasone Infusion in Mitigating Shoulder Pain and Postoperative Nausea and Vomiting Following Laparoscopic Hysterectomy

Design
This study is a randomized, double-blind, phase 2-3 clinical trial with parallel groups conducted on 130 patients undergoing laparoscopic hysterectomy at Taleghani Hospital, Tabriz. Patients will be randomly assigned, using block randomization with blocks of four, into two groups. The intervention group will receive intraoperative intravenous dexamethasone infusion, while the control group will receive placebo (normal saline). The intervention will be administered by the anesthesiologist, and the effect of dexamethasone infusion on postoperative shoulder pain as well as nausea and vomiting will be evaluated and compared.

Settings and conduct
It is a randomized, double-blind, placebo-controlled clinical trial. Three minutes after anesthesia induction, the intervention is administered intravenously over 10 minutes: the intervention group receives dexamethasone (0.2 mg/kg), while the control group receives placebo (normal saline).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 15 to 65 years scheduled for laparoscopic hysterectomy who have provided written informed consent for study participation. Exclusion criteria: Patients with a history of hypertension or known hypersensitivity to dexamethasone.

Intervention groups
In this study conducted at Taleghani Hospital, Tabriz, women undergoing laparoscopic hysterectomy will be randomly assigned to two groups: the intervention group, receiving intraoperative dexamethasone infusion, and the control group, receiving placebo (normal saline). The main outcomes include shoulder pain and postoperative nausea and vomiting.

Main outcome variables
Pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190325043107N84**
Registration date: **2026-08-13, 1405/05/22**
Registration timing: **prospective**

Last update: **2026-08-13, 1405/05/22**
Update count: **0**

Registration date
2026-08-13, 1405/05/22

Registrant information

Name
Mehdi Khanbabayi Gol

Name of organization / entity

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Iran (Islamic Republic of)

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khanbabayimehdi69@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-08, 1405/06/17

Expected recruitment end date
2026-12-08, 1405/09/17

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of Intraoperative Dexamethasone Infusion in Mitigating Shoulder Pain and Postoperative Nausea and Vomiting Following Laparoscopic Hysterectomy

Public title
The Effect of Dexamethasone on Shoulder Pain and Nausea After Hysterectomy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 15 to 65 years Written informed consent for participation in the study
Exclusion criteria:
Hypersensitivity reaction to dexamethasone Patients with a history of hypertension
Age
From **15 years** old to **65 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, with a sample size of 130, participants will be assigned to three groups using permuted block randomization. A block size of four will be employed, utilizing all possible combinations, including: Block 1 (BBAA), Block 2 (AABB), Block 3 (ABAB), Block 4 (BABA), Block 5 (ABBA), and Block 6 (BAAB). To accommodate 130 participants, 33 blocks will be generated using Random Allocation Software, with blocks randomly selected from numbers 1 to 6. For instance, if block 6 and block 2 are selected sequentially, the allocation sequence will be BAABAABB, assigning individuals to Intervention Group (A), Intervention Group (B), and the Control Group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, to ensure proper patient blinding, the medications for groups A and B will be prepared in identical appearance, color, packaging, and administration method, making them indistinguishable to participants. Each medication will be labeled with a unique code (A or B), known only to an independent researcher who is not involved in patient recruitment or evaluation. The envelopes containing the coded medication will be provided to the study investigator in sequential order, without any indication of treatment type. Consequently, both patients and the investigator will remain unaware of group allocation, thus maintaining a practical and effective double-blind design throughout the trial.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Imam Reza Hospital, Azadi Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5165665631
Approval date
2026-07-26, 1405/05/04
Ethics committee reference number
IR.TBZMED.REC.1405.256

Health conditions studied

1

Description of health condition studied
Pain intensity
ICD-10 code
G89.11
ICD-10 code description
Acute pain due to trauma

Primary outcomes

1

Description
Shoulder pain syndrome
Timepoint
Every 12 hours for three days
Method of measurement
Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive an intravenous infusion of dexamethasone (0.2 mg/kg) over 10 minutes, starting 3 minutes after anesthesia induction. Shoulder pain will be assessed using the Visual Analog Scale (VAS), and postoperative nausea and vomiting will be evaluated and recorded at predefined postoperative time points.
Category
Prevention

2

Description
Control group: Patients in the control group will receive an equal volume of normal saline as placebo by intravenous infusion over 10 minutes, starting 3 minutes after anesthesia induction. Shoulder pain will be assessed using the Visual Analog Scale (VAS), and postoperative nausea and vomiting will be evaluated and recorded at the same predefined postoperative time points.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Mansour Rezaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tabriz 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
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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