Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Study of Preemtive Analgestic effect of dexmedetomidine Versus ketamine on pain control after total laparoscopic hysterectomy - a randomized clinical trial study

Protocol summary

Study aim

To evaluate and compare demographic data, post-operative pain intensity, opioid consumption, side effects, quality of recovery, hospital stay duration, intraoperative vital signs, and extubation time among the three study groups.(ketamine,dexmedetomidine and control)

Design

A randomized, double-blind, parallel-group, controlled phase III clinical trial was conducted on 120 patients. Randomization was performed using the card-shuffling method.

Settings and conduct

A randomized, double-blind clinical trial was conducted on 120 TLH patients at Hajar Hospital to compare dexmedetomidine and ketamine against a control. Drugs were administered 10 minutes before incision. Outcomes—including VAS pain scores, opioid use, vital signs, recovery quality, and hospital stay—were monitored for 24 hours postoperatively. Blinding was maintained for patients, anesthesiologists, and statisticians, with only the preparation nurse remaining unblinded.

Participants/Inclusion and exclusion criteria

A: Inclusion Criteria: Patients scheduled for Total Laparoscopic Hysterectomy (TLH). Patients with ASA physical status I or II. No history of addiction to benzodiazepines or opioids, including methadone. B: Exclusion Criteria: Prolonged surgical duration exceeding 180 minutes. Conversion of the surgical procedure to laparotomy. Requirement for blood transfusion during surgery.

Intervention groups

In one group, ketamine at a dose of 0.5 mg/kg and in another group, dexmedetomidine at a dose of 0.5 microgram/kg are administered intravenously after induction of anesthesia and before the start of surgery. In the control group, an equivalent volume of normal saline Is administered

Main outcome variables

Postoperative pain intensity was assessed using the Visual Analog Scale (VAS) at 0, 30 minutes, 1 hour, and 4, 6, 12, and 24 hours post-surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190127042511N3**
Registration date: **2026-06-10, 1405/03/20**
Registration timing: **prospective**

Last update: **2026-06-10, 1405/03/20**
Update count: **0**

Registration date

2026-06-10, 1405/03/20

Registrant information

Name

Alireza Babaeizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Preemtive Analgestic effect of dexmedetomidine Versus ketamine on pain control after total laparoscopic hysterectomy - a randomized clinical trial study

Public title

A comparative study of the effects of ketamine and dexmedetomidine on pain after hysterectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing Total Laparoscopic Hysterectomy (TLH). Patients with an American Society of Anesthesiologists (ASA) physical status classification of I or II. No history of addiction to benzodiazepines or opioids (including methadone).

Exclusion criteria:

Prolonged surgery duration (exceeding 180 minutes). Conversion from laparoscopic to open surgery (laparotomy). Requirement for blood transfusion during surgery.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was performed by convenience sampling. Patients who met the inclusion criteria were enrolled in the study and then randomly assigned to three groups: K, D, and control. For randomization, the card-shuffling method was used. In this method, a number of cards was selected by the researcher for the first group, and the same number of cards was considered for the subsequent groups. The cards were then mixed together (shuffled), one card was drawn, and its allocation was recorded. After being drawn, the card was returned to the set of cards. The cards were then reshuffled, and another card was drawn. This process continued until a random sequence corresponding to the sample size was obtained. One of the advantages of this method is its practicality for multigroup studies. Olson et al. also used this method for randomization in their study.

Blinding (investigator's opinion)

Double blinded

Blinding description

To maintain the double-blind nature of the study, a coding method was used so that neither the performing physician nor the patient was aware of the type of intervention. The medications were prepared and administered by a trained nurse who was not involved in any other part of the study, and the coding procedure was also performed by this nurse. The blinding process was carried out as follows: 1. Individuals blinded to the intervention Patients: were unaware of the type of intervention administered (active drug or placebo). The physician performing the procedure: was blinded to the type of intervention and the composition of the medication contained in the syringes. The statistical analyst: did not have access to the group allocation codes until completion of the primary analysis. 2. Individuals aware of the intervention type Only one trained nurse, who had no role in treatment administration, sampling, patient monitoring, or outcome assessment, was aware of the group allocations. This individual was solely responsible for preparing the medications and coding the syringes and had no involvement in any other stage of the study. 3. Preparation and coding procedure The non-involved nurse prepared the active drug or placebo according to the randomization list. Each syringe was labeled with a unique numerical code without any identifying marks. The volume, color, and appearance of the drug and placebo were made identical to prevent recognition by either the patient or the physician. The correspondence table between the code and intervention type was kept in a sealed envelope and was opened only after completion of data collection. 4. Injection procedure The physician received only the coded syringe and had no information about its contents. The patient also received no information regarding the type of intervention, and the appearance of all syringes was completely identical.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Shahrekord University of Medical Sciences

Street address

Parastar St., Hajar Hospital

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Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
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Approval date
2026-04-22, 1405/02/02
Ethics committee reference number
IR.SKUMS.MED.REC.1405.049

Health conditions studied

1

Description of health condition studied
Study of Preemtive Analgestic effect of dexmedetomidine Versus ketamine on pain control after total laparoscopic hysterectomy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Postoperative pain intensity, measured via the Visual Analog Scale (VAS), was evaluated at 0, 30 minutes, and 1 hour post-surgery, and at 4, 6, 12, and 24 hours after transfer to the ward, across the dexmedetomidine, ketamine, and control groups
Timepoint
at 0, 30 minutes, and 1 hour postoperatively, and at 4, 6, 12, and 24 hours following ward transfer in the dexmedetomidine, ketamine, and control groups.
Method of measurement
Visual Analog Scalescores were assessed on a scale of 0–10 at the indicated time points.

Secondary outcomes

1

Description
Total opioid consumption
Timepoint
Total fentanyl or pethidine consumption over 24 hours
Method of measurement
miligram

2

Description
Postoperative adverse effects
Timepoint
Postoperative adverse effects, including nausea, vomiting, hypotension, and bradycardia, were monitored in all groups.
Method of measurement
Based on the yes/no responses

3

Description
Length of hospital stay
Timepoint
Duration of stay until discharge after surgery
Method of measurement
Time to discharge, measured in days or hours

4

Description
vital sign
Timepoint
Every 15 minutes during the procedure
Method of measurement
Using a monitoring device (blood oxygen saturation, blood pressure in mmHg, and heart rate in beats per minute).

5

Description
Quality of recovery
Timepoint
At the time of discharge from recovery.
Method of measurement
Aldrete score

6

Description
Extubation time
Timepoint
Time from discontinuation of the anesthetic agent to extubation.
Method of measurement
Time from discontinuation of the anesthetic agent to extubation, measured in minutes.

Intervention groups

1

Description
In the first intervention group, general anesthesia is induced using midazolam (0.1 mg/kg), propofol (2.5 mg/kg), fentanyl (3
Category
Prevention

2

Description
“In the second intervention group, general anesthesia was induced using midazolam (0.1 mg/kg), propofol (2.5 mg/kg), fentanyl (3
Category
Prevention

3

Description

In the control group, general anesthesia was induced using midazolam (0.1 mg/kg), propofol (2.5 mg/kg), fentanyl (3

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

Alireza Babaeizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Alireza babaeizadeh

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Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Reseach department

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

Shahre-kord University of Medical Sciences

Full name of responsible person

Alireza Babaeizadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Latest degree

Specialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
De-identified raw dataset containing the variables used for statistical analyses in the present study. All direct patient identifiers will be removed prior to data sharing.

When the data will become available and for how long
From the date of publication until 5 years after publication.

To whom data/document is available
Qualified researchers who provide a scientifically justified request and agree to data confidentiality requirements.

Under which criteria data/document could be used
Data will be available for research and educational purposes only. Commercial use is prohibited. Recipients must agree not to attempt re-identification of study participants.

From where data/document is obtainable
Requests should be directed to the corresponding author via email and will be reviewed on a case-by-case basis.

What processes are involved for a request to access data/document
Requests for access to the data should be submitted in writing to the corresponding author. Requests will be reviewed by the research team for scientific merit, consistency with the study objectives, and compliance with ethical requirements. Upon approval, applicants will be required to sign a Data Use Agreement, after which de-identified data will be made available.

Comments