Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Dexmedetomidine on Hemodynamic Stability and Opioid Requirement in Patients Undergoing Pulmonary Hydatid Cyst Surgery

Protocol summary

Study aim

Evaluation of the effect of dexmedetomidine on hemodynamic stability and opioid requirement in patients undergoing pulmonary hydatid cyst surgery

Design

A controlled, parallel-group, double-blind, block-randomized, phase 3 clinical trial on 40 patients. Block randomization using block sizes of 4 and 6 generated via the SealedEnvelope website will be applied.

Settings and conduct

This study will be conducted at Ghaem Hospital, Mashhad. Patients aged 18–65 undergoing unilateral pulmonary hydatid cyst surgery will be enrolled after informed consent and randomized using block randomization (blocks of 4 and 6 via SealedEnvelope). The intervention group receives dexmedetomidine, and the control group receives normal saline. Hemodynamic parameters are recorded at predefined times. Patients, the assessor, and the statistician are blinded, while the administering anesthesiologist is unblinded for safety.

Participants/Inclusion and exclusion criteria

Age 18 to 65 years, Candidate for unilateral pulmonary hydatid cyst surgery (thoracotomy or VATS), ASA class I–II, Having informed consent to participate.

Intervention groups

Intervention group: Will receive dexmedetomidine intravenously as a 1 µg/kg loading dose over 10 minutes, followed by a 0.5 µg/kg/h infusion until the end of surgery. Control group: Similar to the intervention group, an equivalent volume of Normal Saline will be infused at the same rate.

Main outcome variables

Hemodynamic stability (blood pressure and heart rate); intraoperative opioid consumption; postoperative pain score (VAS); postoperative nausea and vomiting (PONV)

General information

Reason for update

Given that the initial registration of the study in the IRCT system was performed after obtaining the ethics approval and prior to the final approval by the University Research Council, the study start date entered at the time of initial registration was based on the preliminary version of the research proposal. Following further review by the Research Council and the application of the approved revisions, it became necessary to update this information to ensure full consistency between the registered data in IRCT and the final approved version of the research protocol. The purpose of this update was to enhance transparency, scientific accuracy, and complete alignment between the IRCT registration and the final approved protocol as well as the actual conduct of the study. No changes have been made to the overall nature of the study, its primary objectives, or the ethical considerations of the research.

Acronym

IRCT registration information

IRCT registration number: **IRCT20250626066260N1**
Registration date: **2025-11-21, 1404/08/30**
Registration timing: **prospective**

Last update: **2025-12-25, 1404/10/04**
Update count: **1**

Registration date

2025-11-21, 1404/08/30

Registrant information

Name
vahid Nourbakhsh
Name of organization / entity
Country
Iran (Islamic Republic of)
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Email address
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01
Expected recruitment end date
2026-08-23, 1405/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Dexmedetomidine on Hemodynamic Stability and Opioid Requirement in Patients Undergoing Pulmonary Hydatid Cyst Surgery

Public title
Effect of Dexmedetomidine on Hemodynamic Stability and Opioid Requirement in Pulmonary Hydatid Cyst Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 65 years Candidate for unilateral pulmonary hydatid cyst surgery (via thoracotomy or VATS) Physical status ASA class I or II Written informed consent to participate in the study
Exclusion criteria:
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study entitled “The Effect of Dexmedetomidine on Hemodynamic Stability and Opioid Requirement in Patients Undergoing Pulmonary Hydatid Cyst Surgery,” block randomization was used. A total of 10 random blocks with variable block sizes of 4 and 6 and different random sequences were generated using the website https://www.sealedenvelope.com/simple-randomiser/v1/lists . The contents of each block were placed in opaque, sealed, and sequentially numbered envelopes, and all blocks were randomly arranged. As each eligible patient was enrolled, the envelope corresponding to the current block was opened sequentially, and the patient was assigned to one of the two study arms (Dexmedetomidine group or Control group) according to the sequence inside. After completion of the first block, the next block was randomly selected, and this process continued until the last block was completed and the final patient was allocated. Consequently, patients were equally distributed between the two study arms, ensuring proper balance. The unit of randomization in this study was individual, and no stratified randomization was applied. For allocation concealment, the envelopes were prepared opaque, sealed, and sequentially numbered to prevent the investigator from knowing the intervention type prior to patient enrollment. The study was designed as a double-blind trial, in which both patients and the data analyst were blinded to group allocation, while the anesthesiologist administering the drug was aware of the allocation for safety monitoring and management of potential adverse effects.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participant: After receiving full information about the study protocol and providing written informed consent, participants remain unaware of their group allocation. Both dexmedetomidine and placebo solutions are prepared in identical syringes with the same volume and appearance by an independent staff member, ensuring that patients cannot distinguish their assigned intervention. Investigator: The principal investigator does not participate in drug preparation or allocation procedures and remains blinded to group assignments throughout the data collection phase. Allocation codes are kept in sealed envelopes and will only be opened after completion of data analysis. Outcome Assessor: The assessor responsible for recording hemodynamic variables, opioid consumption, postoperative pain scores, and clinical outcomes is fully blinded to the intervention type. The assessor works solely based on patient identification codes and has no access to information about drug assignment or administration.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Imam Reza Hospital Educational, Research and Treatment Center-Mashhad
Street address
Ibn Sina St., Imam Reza Hospital Square, Imam Reza Educational Research and Treatment Center
City
mashhad
Province

Razavi Khorasan

Postal code

9137913316

Approval date

2025-10-27, 1404/08/05

Ethics committee reference number

IR.MUMS.IRH.REC.1404.191

Health conditions studied

1

Description of health condition studied

Pulmonary Hydatid Cyst

ICD-10 code

B67.4

ICD-10 code description

Echinococcus granulosus infection, unspecified

Primary outcomes

1

Description

Systolic and diastolic blood pressure

Timepoint

Before induction of anesthesia; after surgical incision; every fifteen minutes during surgery; in the recovery room

Method of measurement

Measurement of systolic and diastolic blood pressure using invasive and noninvasive automatic blood pressure monitor

2

Description

Heart rate

Timepoint

Before induction of anesthesia; after surgical incision; every fifteen minutes during surgery; in the recovery room

Method of measurement

Measurement of heart rate using an electrocardiographic cardiac monitor

3

Description

Total intraoperative opioid consumption

Timepoint

From the beginning of anesthesia induction until the end of the surgical procedure

Method of measurement

Calculation of the total opioid dose based on values recorded by the anesthesia team in the anesthesia record

Secondary outcomes

1

Description

Postoperative pain score measured by the Visual Analogue Scale

Timepoint

In the recovery room; two hours after surgery; four hours after surgery

Method of measurement

Measurement using a ten-centimeter Visual Analogue Scale for pain assessment

2

Description

Postoperative nausea and vomiting

Timepoint

In the recovery room; two hours after surgery; four hours after surgery

Method of measurement

Clinical observation and documentation of nausea and vomiting events by the recovery room nurse

3

Description

Sedation level assessed by the Ramsay Sedation Scale

Timepoint

In the recovery room; thirty minutes after admission to recovery

Method of measurement

Assessment using the Ramsay Sedation Scale

Intervention groups

1

Description

Intervention group: Includes patients who, after induction of anesthesia, receive dexmedetomidine initially at a dose of 1 µg/kg over 10 minutes, followed by 0.5 µg/kg/h via intravenous infusion until the end of surgery.

Category

Treatment - Drugs

2

Description

Control group: Includes patients who, under the same anesthetic conditions, receive an equivalent volume of normal saline instead of dexmedetomidine at the same infusion rate (placebo). Other anesthetic management and therapeutic interventions are the same as in the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person
Vahid Nourbakhsh

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Ahmadabad Street, Qaem Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Vahid Nourbakhsh

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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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