Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of intraoperative lidocaine infusion compared to placebo on postoperative sleep quality in patients undergoing surgery for right lung hydatid cyst

Protocol summary

Study aim
Determining the effect of intraoperative lidocaine infusion on postoperative sleep quality in right lung hydatid cyst surgery

Design
A randomized controlled clinical trial, parallel-group, triple-blind, phase 3 on 72 patients with hydatid cysts. Randomization is done using the site www.randomization.ir.

Settings and conduct
This study is conducted in Ghaem Hospital, Mashhad University of Medical Sciences. The intervention group received lidocaine infusion during hydatid lung cyst surgery, and the control group received normal saline infusion during surgery. The patient, the principal investigator, the person assessing the outcome, and the person analyzing the data are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with hydatid lung cyst; Patients aged 18-50 years Exclusion criteria: sleep disorder before entering the study (in the patient's self-report or the anesthesiologist's examination); Taking sleeping pills before entering the study; Having a history of addiction

Intervention groups
Intervention group: Infusion of lidocaine during the surgery. Control group: Infusion of normal saline during the surgery.

Main outcome variables
Postoperative sleep quality based on the Pittsburgh Sleep Quality Index score (PSQI) in 7 different areas on the first and third day after surgery.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241021063443N1**
Registration date: **2024-12-23, 1403/10/03**
Registration timing: **prospective**

Last update: **2024-12-23, 1403/10/03**
Update count: **0**

Registration date
2024-12-23, 1403/10/03

Registrant information

Name
Shabnam Niroumand

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-20, 1403/11/01

Expected recruitment end date
2026-01-21, 1404/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of intraoperative lidocaine infusion compared to placebo on postoperative sleep quality in patients

undergoing surgery for right lung hydatid cyst

Public title
The effect of lidocaine on quality of postoperative sleep
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are candidates for lung hydatid cyst surgery Patients aged 18-50 years
Exclusion criteria:
leep disorder before entering the study (in the patient's self-report or the anesthesiologist's examination) Taking sleeping pills before entering the study Having a history of addiction
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**
Randomization (investigator's opinion)
Randomized
Randomization description
Based on the sequence generated by the www.randomizatiom.ir, patients will be randomly assigned to one of two lidocaine or normal saline groups with a ratio of 1:1. Sequential numbers from 1 to 70 will be marked on envelope for each person. 35 sheets of paper marked L (lidocaine group) and 35 sheets marked N (normal saline group) will be sealed inside the envelopes. During the study, the technician opens the envelope and prepares the drugs according to the group specified in the L or N sheet. Normal saline will be exactly the same as lidocaine in terms of color, smell, volume and administration method.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The patients, the anesthetist who administers the drug, and the assistant who collects the data, as well as the person who will analyze the data, will be blinded to the study groups. The protocol and objectives of the study are explained to the patient, and after consent to participate in the study, the nurse prepares the medications according to the order of the prepared packets. Therefore, only the nurse knows whether the patient received lidocaine or placebo. Normal saline is considered a placebo, which is similar in appearance and smell to lidocaine. Therefore, the patient (due to lack of consciousness), the anesthesiologist and assistant who collects information after the operation, as well as the person who analyzes, have no information about the receipt of lidocaine or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Imam Reza Hospital, Mashhad University of Medical Sciences
Street address
Faculty of Medicine, Mashhad University of Medical Sciences, Azadi Square, Mashhad, Khorasan Razavi Province, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2024-08-05, 1403/05/15
Ethics committee reference number
IR.MUMS.IRH.REC.1403.102

Health conditions studied

1

Description of health condition studied
Right lung hydatid cyst
ICD-10 code
B67
ICD-10 code description
Echinococcosis

Primary outcomes

1

Description
Sleep quality after surgery based on Pittsburgh Sleep Quality Index (PSQI) score
Timepoint
Determining Sleep quality before surgery and day 1 and 3 after surgery
Method of measurement
Using the Pittsburgh Sleep Quality Index (PSQI) questionnaire

Secondary outcomes

1

Description
The dose of remifentanil used during the operation
Timepoint
Immediately after surgery
Method of measurement
Measuring the dose of remifentanil used during anesthesia,

2

Description
The presence of cough within 5 minutes after the ex-tube and also the cough scores
Timepoint
Immediately after surgery
Method of measurement
Based on the 4-point Minogue scale

3

Description
The score of pain after the operation
Timepoint
Immediately after surgery
Method of measurement
Based on Visual Analog Scale

4

Description
The occurrence of nausea and vomiting after the operation
Timepoint
Immediately after surgery
Method of measurement
Based on self expression and observation

Intervention groups

1

Description
Intervention group: Continuous infusion of 2 mg/kg/hour of 2% lidocaine ampoule (100 mg in 5cc) produced by Caspian Company during surgery using an JMS Syringe pump SP-500
Category
Rehabilitation

2

Description
Control group: Continuous infusion of 2 mg per kg per hour normal saline during the surgery using an infusion pump -model SP500-JMS
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital- Mashhad University of Medical Sciences
Full name of responsible person
Alireza Sharifian Attar
Street address
Qaem Hospital-Dr. Shariati Square, beginning of Ahmadabad Avenue, Mashhad - Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shabnam Niroumand

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Family Physician

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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
Not applicable

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