

# 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](http://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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3841 2081

##### Email address

niroumandsh@mums.ac.ir

#### 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.randomization.ir](http://www.randomization.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**

Mashhad University of Medical Sciences

#### **Full name of responsible person**

Alireza Sharifian Attar

#### **Street address**

Daneshgah Ave, Mashhad, Iran

#### **City**

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#### **Email**

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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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No 22, South Bozorgmehr 13, Sajjad Blvd

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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## Person responsible for updating data

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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