

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparison of ketorolac-induced analgesia with ketamine in lumbar fusion surgery patients using PCA pain pump

#### Protocol summary

##### Study aim

Comparison of ketorolac-induced analgesia with ketamine in lumbar fusion patients who use PCA pain pump after surgery

##### Design

A clinical trial with parallel groups, double-blind, randomized, phase 3 on 20 patients. The online site <https://www.sealedenvelope.com/> will be used for randomization.

##### Settings and conduct

This study, will be conducted in the Imam Khomeini Teaching-Therapeutic Hospital of Sari in Mazandaran province, 120 patients who are candidates for lumbar fusion surgery who after the operation from PCA pain pumps will participate. The pumps will be marked with numbers 1, 2, and 3, and they will be similar in terms of volume and appearance, which only the project nurse will know about, and other personnel and anesthesiologists will know about it. The three studied groups will not have knowledge.

##### Participants/Inclusion and exclusion criteria

Candidates for lumbar fusion surgery who use PCA pain pump after the operation. Inclusion criteria: willingness of the patient to participate in the study and obtain informed consent, performed lumbar fusion surgery during the research, aged 20 to 75. Exclusion criteria: history of previous spinal surgery, known sensitivity to ketamine or ketorolac

##### Intervention groups

Ketamine vial: Ketamine used in this study in group A, each milliliter of which contains 50 mg of ketamine (500mg/10ml) and is produced by STEROP-Belgium in Germany. Ketorolac vial: Ketorolac used in this study in group B, each milliliter of which contains 30 mg of ketorolac and is produced by Caspian Tamin Company in Iran. Group C: For group C patients, 20 mg of intravenous morphine, which has reached a volume of 100 cc with normal saline, will be given with a PCA pump.

##### Main outcome variables

Pain intensity, the amount of nausea and vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160403027191N5**

Registration date: **2023-10-29, 1402/08/07**

Registration timing: **prospective**

Last update: **2023-10-29, 1402/08/07**

Update count: **0**

##### Registration date

2023-10-29, 1402/08/07

##### Registrant information

##### Name

Abdolmajid Gholinataj Jelodar

##### Name of organization / entity

Mazandaran University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3304 4000

##### Email address

gholinataj54@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-01, 1402/08/10

##### Expected recruitment end date

2023-12-01, 1402/09/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of ketorolac-induced analgesia with ketamine in lumbar fusion surgery patients using PCA pain pump

**Public title**

Comparison of ketorolac-induced analgesia with ketamine in lumbar fusion surgery patients using PCA pain pump

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patient's willingness to participate in the study and obtain informed consent Performing lumbar fusion surgery during the research Being 20 to 75 years old

**Exclusion criteria:**

History of previous spine surgery Known hypersensitivity to ketamine or ketorolac Occurrence of any unusual complications during surgery Substance abuse and psychoactive drugs

**Age**

From **20 years** old to **75 years** old

**Gender**

Both

**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**

Using the online system

<https://www.sealedenvelope.com/>, patients will be randomly divided into three equal groups of 40 people based on the drugs used as follows: BACACB, CAACBB, CAACBB, CABBAC, .... For group A patients, ketamine and morphin; for group B Ketorolac and morphin and for group C only morphine will be given with a PCA pump.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Before starting the study, the list of people will be randomly assigned to 3 study groups using a computer. Based on this list, envelopes are prepared, inside which the name of one of the treatment groups is written based on the list of random numbers. These envelopes will be provided to the first expert, and if the patients meet the entry criteria, an envelope will be opened for each patient and their treatment group will be determined based on it. The drug is prepared for injection by the mentioned expert and is handed over to the second

expert (who does not know the type of drug) and finally the drug is given to the anesthesia assistant performing TAP Block. The completer of the checklist also has no knowledge of the drug group assigned to each patient. The pumps will be marked with numbers 1, 2, and 3 and will be similar in terms of size and appearance, which only the nurse who will be involved in the project will be aware of, and other personnel and anesthesiologists will not be aware of the three studied groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Imam Khomeini Educational and Medical Hospital (RA) Sari - Mazandaran University

**Street address**

Amir Mazandarani Blvd. Administrative Building of Ethics Committee of Imam Khomeini Hospital

**City**

Sari

**Province**

Mazandaran

**Postal code**

48166-33131

**Approval date**

2023-06-07, 1402/03/17

**Ethics committee reference number**

IR.MAZUMS.IMAMHOSPITAL.REC.1402.029

**Health conditions studied****1****Description of health condition studied**

Lumbar fusion

**ICD-10 code**

M43.26

**ICD-10 code description**

Fusion of spine, lumbar region

**Primary outcomes****1****Description**

intensity of pain

**Timepoint**

at 2, 4, 6, 12, 18, 24 hours after surgery

**Method of measurement**

check list

## Secondary outcomes

### 1

#### Description

Time of return from Ileus

#### Timepoint

At times 2, 4, 6, 12, 18, 24 hours after surgery

#### Method of measurement

check list

### 2

#### Description

nausea and vomiting

#### Timepoint

At times 2, 4, 6, 12, 18, 24 hours after surgery

#### Method of measurement

check list

## Intervention groups

### 1

#### Description

Intervention group 1: Ketamine vial: Ketamine used in this study in group A, each milliliter of which contains 50 mg of ketamine (500mg/10ml) and is produced by STEROP-Belgium in Germany.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: Ketorolac vial: Ketorolac used in this study in group B, each milliliter of which contains 30 mg of ketorolac and is produced by Caspian Tamin Company in Iran.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group 3: Group C: For group C patients, 20 mg of intravenous morphine, which has reached a volume of 100 cc with normal saline, will be given with a PCA pump.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini hospital

##### Full name of responsible person

Abdolmajid Gholinataj Jelodar

##### Street address

Department of Anesthesiology, Imam Khomeini hospital, Amir Mazandari street, Sari

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815733971

##### Phone

+98 11 3325 5348

##### Fax

+98 11 3325 5348

##### Email

gholinataj54@mazums.ac.ir

##### Web page address

<https://www.mazums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr Majid Saeedi

##### Street address

Mazandaran University of Medical Sciences, Valiasr Blvd.

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Email

majsaeedi@gmail.com

##### Web page address

<https://www.mazums.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Abdolmajid Gholi Nataj Jelodar

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Position**

Assistant professor

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## Person responsible for updating data

### 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