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
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3335 2725
Fax
+98 11 3335 2725
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

Street address
Mazandaran University of Medical Sciences, Valiasr Blvd.

City
Sari

Province
Mazandaran

Postal code
4815733971

Phone
+98 11 3325 5348

Fax
+98 911 111 5348

Email
gholinataj54@mazums.ac.ir

Web page address
https://www.mazums.ac.ir

Person responsible for scientific 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

Street address
Mazandaran University of Medical Sciences, Valiasr Blvd.

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

Person responsible for updating data

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

Street address
Mazandaran University of Medical Sciences, Valiasr Blvd.

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

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