Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

A Comparative Study on the Use of Ketamine and Apotel Infusion Pump for the Control of Pain After Posterior Fusion Operations

Protocol summary

Study aim
determination and comparison of results of ketamine and apotel infusion pumps for pain control after posterior fusion surgery

Design
clinical trial with control group , with parallel groups , double blinde , randomized

Settings and conduct
background : spinal surgery location : hazrate rasool akram hospital,operative room and department of the neurosurgery method : induction of anesthesia with the same drugs and starting the pain pump with the soecified content of the recovery blind : researcher and department staff and responsible for collecting data by coding instead of writing the drug name

Participants/Inclusion and exclusion criteria
lack of underlying illness lack of adiiction age is within the specified range patient satisfaction normal body mass index

Intervention groups
control group1:use of ketamin control group2:use of apotel

Main outcome variables
pain nausea and vomiting delirium

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190430043430N1**
Registration date: **2019-06-24, 1398/04/03**
Registration timing: **retrospective**

Last update: **2019-06-24, 1398/04/03**
Update count: **0**

Registration date
2019-06-24, 1398/04/03

Registrant information

Name
mohammad ghaemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6435 2326

Email address
ghaemi.m@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-09, 1397/10/19

Expected recruitment end date
2019-04-18, 1398/01/29

Actual recruitment start date
2019-01-19, 1397/10/29

Actual recruitment end date
2019-04-08, 1398/01/19

Trial completion date
2019-04-08, 1398/01/19

Scientific title
A Comparative Study on the Use of Ketamine and Apotel Infusion Pump for the Control of Pain After Posterior Fusion Operations

Public title
" Comparison of Apotel and Ketamine for Pain Control "

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Lack of underlying illness Lack of addiction Age is within the specified range Negative viral markers Body mass index

Exclusion criteria:
Addiction Patient dissatisfaction Background illnesses

Seizure Memory impairment Psychosis

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple random method or a random number table has been used.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient, without knowing the name of the medicine, is simply aware of the administration of the drug. The collector and the medical personnel are not aware of the contents because of the code on the pomp. The researcher does not interfere with the outcome and scoring of pain.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Science., Next to the Tower of Milad., Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-01-09, 1397/10/19

Ethics committee reference number

IR.IUMS.FMD.REC1396.9411174024

Health conditions studied

1

Description of health condition studied

Pain after posterior fusion surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score after the end of the injection pump

Timepoint

0,6,12,18,24,48 hours

Method of measurement

The question of the patient himself

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After extubation, the pain pump containing 0.2 mg/kg of ketamine in the operating room was connected to the patients. Then, the pain score was measured by the VAS standard and in case of sever pain , 0.2 mg/kg pethedine was injected and, if continued, pain was controlled with morphine.

Category

Treatment - Drugs

2

Description

Control group: After extubation, the pain pump containing 1gr apotel in the operating room was connected to the patients. Then, the pain score was measured by the VAS standard and in case of sever pain , 0.2 mg/kg pethedine was injected and, if continued, pain was controlled with morphine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Mohammad ghaemi

Street address

Rasoul Akram Hospital., Niayesh Ave., Sattarkhan Ave.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr.Seyed Kazem Malakouti

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Research and Technology Dept., Iran University of Medical Science., Next to the Milad Tower., Hemmat Highway

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research@iums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mohammad Ghaemi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Iran University of Medical Sciences

Full name of responsible person
Nasim Nikoubakht

Position
Assistant professor

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Specialist

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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

No - There is not 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