

# 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

**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 pump. 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****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

**Contact**

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Iran University of Medical Sciences

**Full name of responsible person**

Nasim Nikoubakht

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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**Email**

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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