

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of analgesic effect of low dose of ketamine vs. methadone on opioid abusers undergoing surgery

Protocol summary

Study aim

Determining the effect of low dose ketamine compared to methadone on pain control in addicts after surgery

Design

A clinical trial with a control group, parallel groups, single-blind, randomized, phase 2, 100 patients. Block method is used for randomization

Settings and conduct

Patients are referred to Imam Reza Hospital in Mashhad as candidates for abdominal surgeries. At the end of the operation, after discontinuing all drugs, the ketamine group receives 0.5 mg per kg of ketamine every 6 hours intravenously and the methadone group receives 5 mg intramuscularly every 8 hours. An anesthesia assistant or trained nurse accompanies the patient throughout the procedure and at the time of discharge. We will use the Verbal Scoring System (NRS) to assess pain. Patients are prescribed every 3 hours to record the pain score and at the end of 24 hours for the total morphine and the highest postoperative pain score is reported in the ICU. Also, in the questionnaire sheet, their pain number and if there are any side effects due to drugs or delirium due to ketamine will be recorded. This visit was performed by a person who will not be aware of the type of preoperative medication.

Participants/Inclusion and exclusion criteria

Addicted patients who are candidates for GA abdominal surgery who need ICU for postoperative period. Age between 20 to 65 years. History of daily drug use for the past 6 months

Intervention groups

Intervention group (Ketamine group): Ketamine in ICU 0.5 mg per kg every 6 hours intravenously and if there is a pain score greater than 3 is prescribed. In the control group, 5 mg of methadone is administered every 8 hours.

Main outcome variables

Pain, time, gastrointestinal complications, respiratory apnea, hyperalgesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111212008384N8**

Registration date: **2022-02-24, 1400/12/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-24, 1400/12/05**

Update count: **0**

Registration date

2022-02-24, 1400/12/05

Registrant information

Name

Arash Peivandi Yazdi

Name of organization / entity

Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of low dose of ketamine vs. methadone on opioid abusers undergoing surgery

Public title

Comparison of ketamine and methadone in pain control of addicts after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Addicted patients who are candidates for GA abdominal surgery require special postoperative care Age between 20 to 65 years History of daily drug use for the past 6 months

Exclusion criteria:

Known drug allergy to ketamine or methadone History of hypertension or PAP History of severe systemic disease History of psychiatric illness high ICP History of alcohol and psychotropic substances Prohibition of intramuscular injection Pregnancy

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **220**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is used. In this method, 55 blocks of 4 are selected through the relevant sites. Then 110 letters A are prepared and 110 letters B are prepared. Opaque envelopes are also used for concealment. 220 envelopes are prepared and the letters A and B are placed in the extracted blocks, respectively. The envelopes are sealed and given to the patient's recipient. Each patient is given an envelope (in order) at the time of referral, which the patient will provide to the doctor. The letter A represents the methadone group and the letter B represents the ketamine group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the person evaluating the amount of pain will be unaware of the allocating people in the two study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Department of anesthesiology, Imam Reza hospital, Shariati Square

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Razavi Khorasan

Postal code

9137913316

Approval date

2021-01-19, 1399/10/30

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.150

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

At the beginning, every 3 hours, after 24 hours

Method of measurement

Using the Verbal Scoring System (NRS) we will use zero as the minimum and 10 as the maximum number of pain.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ketamine will be administered in the ICU 0.5 mg per kg every 6 hours intravenously

Category

Treatment - Drugs

2

Description

Control group: In the control group, 5 mg of methadone

is administered every 8 hours
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Mashhad University of
Medical Science
Full name of responsible person
Majid Ghayour Mobarhan
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Ghoreishi apartment, Daneshgah street, Mashhad,
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Web page address
<https://v-research.mums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Mashhad University of
Medical Science

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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data can potentially be shared after people are not identified

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

After correspondence with the scientific person in charge of the project and after the publication of the article, by preserving the intellectual rights of the authors, it is possible to access the data and perform analysis on the information.

From where data/document is obtainable

To request data, you can correspond by email to the person in charge of the scientific plan

What processes are involved for a request to access data/document

To request data, you can correspond by email to the person in charge of the scientific plan

Comments