Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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peivandia@mums.ac.ir

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

City
Mashhad

Province
Razavi Khorasan

Postal code
۹۱۳۷۹۱۳۳۱۶

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

Full name of responsible person

Arash Peivandi Yazdi

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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

Street address

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Arash Peivandi Yazdi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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