

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of ketamine infusion on the control of pain and hemodynamics of addicted patients in cardiac surgery

Protocol summary

Study aim

Evaluation of the relationship between ketamine infusion on pain control and hemodynamics in opiate addicts undergoing cardiac surgery

Design

Since the present study is a clinical trial of efficacy determination, the following formula was used to calculate sample size. $A = 0.05$ and $\beta = 0.20$ were used to calculate the sample size and the difference was considered to be 2%. $n = 2 * [1.645 + 0.845 / 0.4 - 0.1] 2 * 0.4 (0.6) = 33$ In order to increase the accuracy of the study, at the end of each group, 5 patients will be examined

Settings and conduct

Operating room and icu

Participants/Inclusion and exclusion criteria

1-Fill out the consent form and desire to participate in the study 2- At least one year history of opiate use 3. Age less than 75 years 4- No history of mental illness

Intervention groups

A single dose of continuous-dose ketamine (30mcg / kg / min) after induction of anesthesia until the end of surgery and continued with a dose (5mcg / kg / min) up to 6 hours after surgery.

Main outcome variables

Pain and hemodynamic changes during and after anesthesia in addicts are difficult to control and usually require high doses of opioids. Patients are resistant to opioids used in anesthesia and ketamine affects various opioid and non-opioid receptors and produces analgesic effects. In opiate-dependent patients, the effect of non-opioid receptors on the sensitivity of these patients to This drug causes analgesia and consequently results in less use of opi The vids will ache better during and after surgery and control.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190731044389N1**
Registration date: **2019-08-20, 1398/05/29**
Registration timing: **prospective**

Last update: **2019-08-20, 1398/05/29**

Update count: **0**

Registration date

2019-08-20, 1398/05/29

Registrant information

Name

Payman Rezagholi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3318 0980

Email address

paimanrezagholy@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ketamine infusion on the control of pain and hemodynamics of addicted patients in cardiac surgery

Public title

The effect of ketamine infusion on the control of pain and hemodynamics

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Fill out the consent form and desire to participate in the study At least one year history of opiate use Age less than 75 years No history of mental illness

Exclusion criteria:

1. People whose pumping time exceeds 100 minutes
Extending the extubation time Return to the operating room for some reason after the operation Unusual bleeding during surgery and after surgery Extreme and prolonged hypotension Surgery without cardiopulmonary pump Return to the operating room for some reason after the operation Patient's personal desire to quit research and not continue to cooperate without giving an explanation Kidney failure Liver failure

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Using simple random method and random number table, patients will be selected by available method and divided into two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is a double-blind clinical trial and will be drawn and infused by a nurse with the same syringe as ketamine and normal saline, and the researcher will have no information about the contents of the syringes until the end of the study. Also, the nurse will not be aware of the study process and will only assist in the preparation of the medication

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah Hospital

City

tehran

Province

Tehran

Postal code

666141-83834

Approval date

2019-07-20, 1398/04/29

Ethics committee reference number

IR.BMSU.REC.1398.118

Health conditions studied

1

Description of health condition studied

heart surgery

ICD-10 code

Y83.4

ICD-10 code description

Other reconstructive I

Primary outcomes

1

Description

Drug use in control and control groups

Timepoint

Before surgery up to 48 hours after surgery

Method of measurement

Vas and demographic questionnaire

Secondary outcomes

1

Description

Hemodynamic changes during surgery

Timepoint

Before surgery up to 48 hours after surgery

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Ketamine recipient

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

پیمان رضاقلی

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Baqiyatallah Hospital

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aheartcenter@gmail.com

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https://research2.bmsu.ac.ir/homepage/homePage.action#_contactus

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Vahidkariminezhad

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

PAIMAN REZAGHOLY

Position

Student

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available