

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

: Low-dose ketamine effectiveness in acute coronary syndrome with opioid unresponsive or hemodynamically unstable patients

Protocol summary

Study aim

Effect of low dose ketamine on pain control in patients with opioid-resistant in acute coronary syndrome or with unstable hemodynamics referred to the emergency department of Shahid Rajaei Hospital in Karaj in 2020-2021

Design

140 patients with a diagnosis of acute opioid-resistant coronary syndrome or with unstable hemodynamics referred to the emergency department of Rajaei Hospital in Karaj will be examined and admitted according to the inclusion and exclusion criteria. Then for patients in both groups after standard treatment in the intervention group intravenous ketamine with a dose of 0.1-0.3 mg / kg and repeated as a bolus and 20 minutes later. For the control group opioid is prescribed with the same dose .

Settings and conduct

This study is such that patients who are candidates for inclusion in the study, after examination in terms of inclusion and exclusion criteria and obtaining informed consent using Block Randomization and software will be divided into two groups 1-intervention and 2-control and Based on the random serials produced Blinding: The method of blinding is that the five-digit serial numbers produced in the process of random allocation are placed in sealed envelopes and assigned by an independent person from the research team and by telephone to each of the eligible individuals.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age over 18 years - Age under 65 years
Exclusion criteria: - Age less than 18 years - Age over 65 years

Intervention groups

Intervention group: A group of patients receiving low-dose ketamine as part of treatment (0.1-0.3 mg / kg)
Control group: A group of patients who do not receive low-dose ketamine as part of treatment.

Main outcome variables

Determination

of pain relief in patients with acute opioid-resistant coronary syndrome or unstable hemodynamics in the intervention group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190611043864N1**

Registration date: **2020-12-30, 1399/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-30, 1399/10/10**

Update count: **0**

Registration date

2020-12-30, 1399/10/10

Registrant information

Name

Ali Lotfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3224 8154

Email address

ali23686@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-14, 1399/06/24

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
: Low-dose ketamine effectiveness in acute coronary syndrome with opioid unresponsive or hemodynamically unstable patients

Public title
Low-dose ketamine effectiveness in acute coronary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
-Age above 18 years old -Age below 65 years old - Satisfaction for participating in study -Patients with acute coronary syndrome that has VAS more or equal to 9 and unstable haemodynamic (Systolic blood pressure less than or equal to 90 mm Hg or diastolic blood pressure less than or equal to 60 mm Hg or both) -Lack of precedent of sensitiveness to ketamine
Exclusion criteria:
-Dissatisfaction for participating in study -Age below than 18 years old -Age above than 65 years old -Weight below than 40 Kg -Drug or alcohol intoxication -Active psychiatric disorder -Heart rate more than 100 per minute

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are readily available in the study (recruitment) and are divided into two groups of intervention and control based on random allocation (random block). Block Randomization method using the site (<https://www.sealedenvelope.com/simple>) has been used to assign samples to the intervention and control groups. 35 blocks of 4 with a specific code are prepared and used.

Blinding (investigator's opinion)
Single blinded

Blinding description
The method of blinding is that the five-digit serial numbers produced in the process of random allocation are placed in sealed envelopes and assigned by an independent person from the research team and by telephone to each of the eligible individuals.

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Research Ethics Committee of Alborz University of Medical Sciences
Street address
unit4,No42,17th shahrivar ave,shahid Beheshti st
City
Karaj
Province
Alborz
Postal code
3134915964
Approval date
2020-05-30, 1399/03/10
Ethics committee reference number
IR.ABZUMS.REC.1399.104

Health conditions studied

1
Description of health condition studied
Acute Coronary Syndrome
ICD-10 code
I60-I69
ICD-10 code description
Ischaemic heart diseases

Primary outcomes

1
Description
Pain
Timepoint
0-15 minutes -30 minutes -45 minutes
Method of measurement
10-visual analogue scale (VAS) - by the patient

2
Description
The amount of pethidine consumed
Timepoint
0, 15, 30, 45 minutes
Method of measurement
Based on milligram of drug used. observe and record files

3

Description

Confusion

Timepoint

0, 15, 30, 45 minutes

Method of measurement

History and physical examination

4

Description

heart rate

Timepoint

0, 15, 30, 45 minutes

Method of measurement

physical examination

5

Description

Systolic blood pressure

Timepoint

0, 15, 30, 45 minutes

Method of measurement

sphygmomanometer cuff based on millimeter of Hg

6

Description

Diastolic blood pressure

Timepoint

0, 15, 30, 45 minutes

Method of measurement

sphygmomanometer cuff based on millimeter of Hg

7

Description

Drowsiness

Timepoint

0, 15, 30, 45 minutes

Method of measurement

History and physical examination

8

Description

Vertigo

Timepoint

0, 15, 30, 45 minutes

Method of measurement

History and physical examination

9

Description

Fatigue

Timepoint

0, 15, 30, 45 minutes

Method of measurement

History and physical examination

10

Description

Headache

Timepoint

0, 15, 30, 45 minutes

Method of measurement

History and physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group of patients receiving low-dose ketamine as part of treatment (0.1-0.3 mg / kg)

Category

Treatment - Drugs

2

Description

Control group: A group of patients who do not receive low-dose ketamine as part of treatment (0.1-0.3 mg / kg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Rajaei Hospital

Full name of responsible person

Ali Lotfi

Street address

Shahid Beheshti St. Shahid Rajaei Street

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Alborz

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3197635141

Phone

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Fax

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Email

Rajaei@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Dr.Somayeh Dehghan Benadkoki

Street address

No. 42, , 17 Shahrivar Alley, Shahid Beheshti St.Unit 4

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Email

ali23686@yahoo.com

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

Yes

Title of funding source

Karaj 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**

Karaj University of Medical Sciences

Full name of responsible person

Dr. Mehdi Rezaei Kojani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Phone

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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

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Part of the data can be shared.

When the data will become available and for how long

After the end of the study

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to carry out complementary research projects

From where data/document is obtainable

Ali Lotfi

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

Request from me or my teachers

Comments