Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of ketamine administration in controlling agitation in patients with opioid withdrawal syndrome at Loghman Hakim Hospital: a clinical trial study

Protocol summary

Study aim

Evaluation of the effect of ketamine on the control of agitation caused by substance withdrawal syndrome using a randomized clinical trial design

Design

A phase lll , randomized, double - blind, controlled clinical trial was conducted on 60 patients.

Settings and conduct

Eligible patients presenting to the study center will be recruited using convenience sampling. Participants will then randomly assigned to either ketamine or midazolam group using block randomization . Drug administration and assessment of agitation will be performed by separate personnel who are blinded to the treatment allocation , ensuring a double-blind study.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 70 years presenting with moderate to severe agitation associated with substance withdrawal syndrome were included in the study .patients with history of hypersensitivity ketamine or benzodiazepines misuse ,or sever hepatic or renal impairment were excluded from the study

Intervention groups

Intervention group:was administered intravenously at a dose of 0.6 mg/kg over a period of one hour Control group: Midazolam was administered as an initial dose of 0.1 mg/kg ,followed by a continuous infusion 0.1 mg/kg/h .

Main outcome variables

1. To provide robust clinical evidence supporting the use of ketamine as an effective therapeutic option for controlling agitation in patients experiencing substance withdrawal syndrome. 2. To improve the treatment protocols of the Emergency Department and Poisoning Unit at Loghman Hakim Hospital for the management of patients with severe agitation secondary to withdrawal syndrome. 3. To reduce the need for conventional sedatives, such as benzodiazepines, and minimize the adverse effects associated with their use. 4. To enhance patient safety through more rapid and effective control of agitation and by reducing high-risk behaviors associated with withdrawal syndrome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091116002717N4**
Registration date: **2026-09-05, 1405/06/14**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-05, 1405/06/14**
Update count: **0**

Registration date

2026-09-05, 1405/06/14

Registrant information

Name

Babak Mostafazadeh

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 5540 9534

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mstzbmd@sbmu.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date

2027-01-20, 1405/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of ketamine administration in controlling agitation in patients with opioid withdrawal syndrome at Loghman Hakim Hospital: a clinical trial study

Public title

Investigation the effect of ketamine on agitation in substance withdrawal syndrom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients aged 18 to 70 years with substance withdrawal syndrome accompanied by moderate to severe agitation

Exclusion criteria:

Patients with a history of ketamine or benzodiazepine abuse or hypersensitivity to ketamine or benzodiazepines The presence of trauma or a life-threatening medical condition Sever hepatic or renal impairment Concomitant use of medications that interact with ketamine or benzodiazepines

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization-Eligible patients who provide informed consent will be allocated to the intervention group (ketamine) or the control group (midazolam) using block randomization with a 1:1 allocation ratio. To maintain a balanced number of participants in the two groups, blocks of four Will be used. Each block will contain two allocations to the ketamine group and two allocations to the midazolam group, with the order of allocation randomly determined. The random allocation sequence will be generated using a computer-generated randomization program, and eligible patients will be assigned sequentially to one of the two groups according to the predetermined allocation sequence. A total of 60 patients will be enrolled, with 30 participants expected to be allocated to each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug administration and agitation assessment will be performed by separate individuals who are blinded to the treatment allocatin

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, Deputy for Research and Technology, Shahid Beheshti University of Medical

Street address

Faculty of Medicine, Shahid Beheshti University of Medical Sciences, Yadegar-e Emam (Shahid Chamran) Expressway, Yemen Street, Daneshjoo Boulevard, Koodakyar Dead End, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2026-07-26, 1405/05/04

Ethics committee reference number

IR.SBMU.RETECH.REC.1405.276

Health conditions studied

1

Description of health condition studied

Agitation due to substance withdrawal

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of withdrawal-related agitation

Timepoint

0-15-30-60-120 min

Method of measurement

Using the Richmond Agitation-Sedation Scale(RASS)

Secondary outcomes

1

Description
Rescue medication requirement
Timepoint
Within 30 minutes after ketamine administration
Method of measurement
Recorded as yes/no

2

Description
Adverse effect of ketamine
Timepoint
Up to 2h after administration
Method of measurement
Recording symptoms such as nausea-vomiting-hallucination

Intervention groups

1

Description
Intervention group:patients receiving ketamine . In the intervention group, ketamine will be administered intravenously at a dose of 0.6 mg/ kg over a period of one hour. In the control group, midazolam will be administered intravenously at an initial dose of 0.1 mg/kg, followed by continuous intravenous infusion of midazolam at a rate of 0.1 mg/kg/hour. Drug administration and patient monitoring will be performed according to the study protocol and standard patient monitoring and care procedures.
Category
Treatment - Drugs

2

Description
Control group: patient receiving midazolam
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان لقمان حکیم
Full name of responsible person
لیدا حاتمی
Street address
Loghman Hakim Hospital,Kamali Street , South kargar Street , Chaharrah-e Lashgar, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1336616351
Phone
+98 21 5541 9005
Email
lidahatami@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.afshin zarghi
Street address
Shahid Beheshti University of Medical Sciences, Daneshjoo Boulevard, Yemen Street, Shahid Chamran Highway, Tehran, Iran.
City
Tehran
Province
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Postal code
1985717443
Phone
+98 21 23871
Email
lidahatami@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mostafazade babak
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Toxicology
Street address
Loghman Hakim Hospital, Kamali Street, South Kargar Street, Chaharrah-e Lashgar, Tehran, Iran.

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Person responsible for updating data

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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
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
Title and more details about the data/document
Only anonymized and de-identified clinical and research data, including demographic and outcome data, may be shared for scientific purposes.
When the data will become available and for how long
Six months after publication of the results
To whom data/document is available
Researchers
Under which criteria data/document could be used
Descriptive and inferential analyses related to the study objectives, including comparison of RASS scores, need for rescue medication, and adverse events between the study groups, are permitted on anonymized and de-identified data.
From where data/document is obtainable
Loghman Hakim Hospital, Kamali Street, South Kargar Street, Chaharrah-e Lashgar, Tehran, Iran.
What processes are involved for a request to access data/document
Upon receipt of a request through official correspondence with the hospital, the relevant documents will be provided to the requester as soon as possible, following verification of the requester's identity and eligibility.
Comments