Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparative study of the effects of ketamine with midazolam on reducing suicidal ideation in suicide attempters undergoing intubation treatment

Protocol summary

Study aim
Determining the frequency distribution of suicidal thoughts in ketamine recipients and comparing it with midazolam recipients in suicide attempters undergoing intubation treatment

Design
The Clinical trial with control and intervention group, double-blind, randomized, on 42 patients, Permuted block randomization will be used.

Settings and conduct
The study will be conducted in the psychiatric clinic of Khorshid Hospital. Referrals will be placed into two intervention and control groups using a block randomization method. The intervention group will be given ketamine and the control group will be given midazolam. The psychiatrist and the patient will not be aware of the type of medication given to each referral, and only the statistician will be aware.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients between 18 and 65 years of age who have been admitted to the Intensive Care Unit of Khorshid Hospital due to suicide, consent from the guardian or legal supervisor. Exclusion criteria: ECG with extensive abnormal changes, history of ketamine abuse or dependence

Intervention groups
Intervention group: Intubated suicide attempters will receive intravenous racemic ketamine hydrochloride from Exir Company at a dose of 0.5 mg/kg in 100 cc of normal saline, infused over 45 minutes. Control group: Intubated suicide attempters will receive intravenous midazolam from Exir Company at a dose of 0.3 to 0.5 mg/kg in 100 cc of normal saline, infused over 40 minutes.

Main outcome variables
Suicidal ideation score on the Beck-21 Suicidal Ideation Questionnaire scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211121053132N3**
Registration date: **2025-08-11, 1404/05/20**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-11, 1404/05/20**
Update count: **0**

Registration date
2025-08-11, 1404/05/20

Registrant information

Name
Ali Shariat

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-12, 1404/04/21

Expected recruitment end date
2025-08-22, 1404/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effects of ketamine with midazolam on reducing suicidal ideation in suicide attempters undergoing intubation treatment

Public title
Comparing the effects of ketamine with midazolam on suicidal ideation in suicide attempters

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients between 18 to 65 years, who were admitted to the intensive care unit of Khorshid Hospital due to suicide Consent from the guardian or legal supervisor

Exclusion criteria:
ECG with extensive abnormal changes History of ketamine abuse or dependence

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling method: Patients are selected consecutively. The first two people who meet the conditions for entering the sample are selected and form a block, and these blocks continue until the sample size is reached. (We will conduct a trial for both people in the manner that will be mentioned and record all the steps and results of the questionnaire, so the purpose of reaching the sample size is not in one day but in a period of time that depends on the number of clients and hospitalized patients.) Within these blocks, people are randomly assigned to either the first intervention or the second intervention, which is done using a random number table. If the number is from 0 to 4, the first person receives the first drug, and otherwise (5-9) the second person. These people are sorted within the block by national code and become the first and second patients. (The larger 10-digit number is the first patient and the smaller number is the second patient).

Blinding (investigator's opinion)
Double blinded

Blinding description
The two study medications, which were randomly assigned to the patients forming each block using a random number table, are placed in fully sealed envelopes. The participant number in the study (from 1 to 42), corresponding to the medication, is written on the envelope. An experienced nurse who is not a member of the study team, and therefore has no conflict of interest, is selected and instructed to prepare the medication for injection in a separate room out of sight of the researchers and study participants. (Since the nurse administering the injection is not a member of the study team, the name or code of the medication is written on the envelope for the nurse's information). Since the patient is under anesthesia and unaware of the medication they receive, and the study investigator (a psychiatrist who is the primary designer of the research question and potentially exposed to conflicts of interest) is also unaware of which medication each patient receives, blinding has been implemented. Blinding was not applied to the person responsible for data collection, the outcome assessor, and the statistical consultant. It is noteworthy that informed consent was obtained from the patient's guardian or legal supervisor prior to participation, and after the patient regains consciousness, they will be informed about their participation in the study—though they will not be informed of the specific medication they received.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

Street address
Research Ethics Committees of School of Medicine , Isfahan University of Medical Sciences , Hezar Jarib Ave, Azadi Sq

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8174673461

Approval date
2023-10-31, 1402/08/09

Ethics committee reference number
IR.MUI.MED.REC.1402.290

Health conditions studied

1

Description of health condition studied
Suicidal thoughts

ICD-10 code
R45.8

ICD-10 code description
Other symptoms and signs involving emotional state

Primary outcomes

1

Description
Suicidal ideation score on the Beck-21 Suicidal Ideation Questionnaire scale
Timepoint
After patients are fully conscious (about 24 to 48 hours after receiving the medication)
Method of measurement
Beck-21 Suicidal Ideation Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intubated suicide attempters will receive intravenous racemic ketamine hydrochloride from Exir Company at a dose of 0.5 mg/kg in 100 cc of normal saline, infused over 45 minutes.
Category
Treatment - Drugs

2

Description
Control group: Intubated suicide attempters will receive intravenous midazolam from Exir Company at a dose of 0.3 to 0.5 mg/kg in 100 cc of normal saline, infused over 40 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorshid hospital
Full name of responsible person
Dr Ali shariat
Street address
Psychiatry clinic, Khurshid hospital, Ostandari Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Azade Erfan
Position
intern
Latest degree
A Level or less
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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