Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

The effect of single dose of ketamine injection in reducing suicidal ideation in type 1 bipolardisorder patients in the depressive phase

Protocol summary

Study aim
The effect of single dose of ketamine injection in reducing suicidal ideation in type 1 bipolardisorder patients in the depressive phase

Design
The study will be double blind and clinical trial.124 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3.

Settings and conduct
Patients With type 1 bipolardisorder patients in the depressive phase in Amirkabir Hospital in Arak are divided into 4 groups by simple randomization with blocks.The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria
Conditions for entering the study: patients with bipolar disorder type 1 in the depressive phase according to DSM5 criteria and having suicidal thoughts, not using drugs in the last one month, not receiving electric shocks in the last month and during the last hospitalization, 15 to 65 years old absence of mental retardation, absence of underlying disease, absence of history of stroke, seizures, brain tumor, dementia and being in the delirium phase, absence of history of head injury and loss of consciousness, absence of any drug and alcohol use in the past month Conditions for withdrawal from the study: lack of consent of the patient or the guardian to participate in the study, allergy to the drug

Intervention groups
In one group, intravenous ketamine (0.5 mg per kilogram of intravenous ketamine over 30 minutes) will be used, and in the other group, normal saline (500 ml of normal intravenous saline) will be used as a placebo. And the Beck questionnaire is evaluated before injection, 2 hours after injection, 24 hours after and 72 hours after injection.

Main outcome variables
Suicidal ideation score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N182**
Registration date: **2023-05-07, 1402/02/17**
Registration timing: **prospective**

Last update: **2023-05-07, 1402/02/17**
Update count: **0**

Registration date
2023-05-07, 1402/02/17

Registrant information

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Fariba Farokhi

Name of organization / entity
Arak University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-20, 1402/02/30

Expected recruitment end date
2024-05-19, 1403/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of single dose of ketamine injection in reducing suicidal ideation in type 1 bipolardisorder patients in the depressive phase

Public title
The effect of single dose of ketamine injection in reducing suicidal ideation in type 1 bipolardisorder patients in the depressive phase

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with bipolar disorder type 1 in the depressive phase according to DSM5 criteria and having suicidal thoughts No drug use in the last month. Not receiving electric shock during the last month and during recent hospitalization. 15 to 65 years No mental retardation Absence of underlying disease No history of stroke, seizure, brain tumor, dementia and being in delirium phase No history of head injury and loss of consciousness Not using all kinds of drugs and alcohol in the past month

Exclusion criteria:
Lack of consent of the patient or guardian to participate in the study Drug sensitivity

Age
From **15 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **124**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into2 groups using a permuted balanced block randomization method with the size of blocks 4. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (https://www.sealedenvelope.com/). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be double-blind, considering that both groups receive the drug in the form of serum and the form of injection in both groups is the same, the patients will not know what treatment they are receiving. Also, on this basis, in order to divide the patients, an envelope was used, which was determined based on the letters A (intervention group) and B (placebo group), and based on this, the patient and the doctor were blinded to the patient group. After obtaining the consent of the guardian, the patient enters the study and the medicine is prepared by the anesthesiologist and given to the anesthesiologist and the injection is done under the supervision of the anesthesiologist and psychiatry resident. Based on this, the patients and the psychiatric assistant and the anesthesia technician are blind to the type of drug and the group of patients, but the anesthesiologist who prepares the drugs and provides them to the assistant and the technician for injection is unaware of the type of drugs.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Approval date
empty

Ethics committee reference number

2

Ethics committee

Name of ethics committee
Ethics comittee of Arak University of Medical Sciences

Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak

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Markazi

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3848176941

Approval date
2023-01-09, 1401/10/19

Ethics committee reference number
IR.ARAKMU.REC.1401.311

Health conditions studied

1

Description of health condition studied
type 1 bipolardisorder patients in the depressive phase

ICD-10 code
F06.31

ICD-10 code description
Mood disorder due to known physiological condition with depressive features

Primary outcomes

1

Description
Suicidal ideation
Timepoint
Start of the study, 2, 24 and 72 hours after the start of the study
Method of measurement
Beck Suicidal Ideation Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They will receive intravenous ketamine (0.5 mg for every kilogram of intravenous ketamine over 30 minutes).
Category
Treatment - Drugs

2

Description
Control group: normal saline (500 millileter of normal intravenous saline) will be used as a placebo.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkabir hospital
Full name of responsible person
Dr Hamidreza Jamilian
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Sponsors / Funding sources

1

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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
Arak 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
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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