

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Efficacy of add on trial of single or double dose of intravenousKetamine to usual treatment with mood stabilizers in treating bipolardepression

Protocol summary

Study aim

The purpose of this study is to investigate the effectiveness of adding one injection and two intravenous injections of ketamine to mood stabilizing treatments in the treatment of bipolar depression with a control group.

Design

A clinical trial with control and intervention groups, with parallel groups, blinded, randomized, phase 4 on 60 patients. The rand function of Excel software was used for randomization

Settings and conduct

Ibn Sina Hospital, Mashhad, diagnosed with bipolar depression

Participants/Inclusion and exclusion criteria

Inclusion criteria include: age 18 to 65 years; Patients who have been treated with full-dose anti-depressants for at least 8 weeks; Completing the written informed consent form. Inclusion criteria: substance abuse

Intervention groups

One group is injected with 0.5 mg/kg body weight of ketamine (within 40 minutes) and the control group is injected with normal saline. Patients' symptoms are evaluated using criteria at the beginning of the study, 90 minutes and days 1, 7, 30 and 60 after injection. Also, Hamilton's depression and Beck's anxiety criteria will be used to evaluate patients at the same time.

Main outcome variables

Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101130005280N58**

Registration date: **2022-10-06, 1401/07/14**

Registration timing: **prospective**

Last update: **2022-10-06, 1401/07/14**

Update count: **0**

Registration date

2022-10-06, 1401/07/14

Registrant information

Name

Raheleh Nejati

Name of organization / entity

Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2540

Email address

nejatir2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2022-10-25, 1401/08/03

Expected recruitment end date

2023-10-25, 1402/08/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of add on trial of single or double dose of intravenousKetamine to usual treatment with mood stabilizers in treating bipolardepression

Public title

Efficacy of ketamine in the treatment of depressive

disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have received a depressive episode by a doctor diagnosing bipolar disorder (one and two) In the last two weeks (since the start of sampling) there has been no significant change in their medication regimen

Exclusion criteria:
Patients with severe physical illness (especially hypertension) History of substance use and dependence in the past month

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

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
This is how random numbers are prepared with the help of Randomize.com. According to the number of research samples, a number of envelopes with wrappers Alumni (in order to avoid the clarity of the contents of the envelopes), are prepared and each of the random sequences created on a card is recorded and the cards inside the envelopes are better named. In order to maintain a random sequence, also on the outer surface of the envelopes. The issuance number is done in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the envelopes have the odd number of the control group and the envelopes have an even number.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Random numbers table

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee of Mashhad University of Medical sciences

Street address

Qoreishi Building, Daneshgah St.

City

Mashhad

Province

Razavi Khorasan

Postal code

123456

Approval date

2014-07-23, 1393/05/01

Ethics committee reference number

922343

Health conditions studied

1

Description of health condition studied

Bipolar depression

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

depression

Timepoint

base line and 90 minutes, 1 day, 7 days, 30 days and 60 days after infusion

Method of measurement

Hamilton depression questionnaire

2

Description

anxiety

Timepoint

base line and 90 minutes, 1 day, 7 days, 30 days and 60 days after infusion

Method of measurement

Beck anxiety scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group will receive normal saline.

Category

Placebo

2

Description

Intervention group: Ketamine in dose of 0.5 milligram/kilogram will be infused over 40 minutes in case group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn e Sina Hospital

Full name of responsible person

Dr Mahnaz Abedian.

Street address

Ibn e Sina Hospital, Bu-Ali Sq, Amel Blvd, Mashhad, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Ali Talaei

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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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