Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 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 Randomaize.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.
City
Mashhad
Province
Razavi Khorasan
Postal code
123456
Phone
+98 51 3764 7197
Email
fahimeh.afzaljavan@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour
Street address
Qoreishi Building, Daneshgah St.
City
Mashhad
Province
Razavi Khorasan
Postal code
123456
Phone
+98 51 3841 2081
Email
ramresearch@mums.ac.ir
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
Street address
Ibn e Sina Hospital, Bu-Ali Sq, Amel Blvd, Mashhad, Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
1234654
Phone
+98 51 3711 2701
Fax
Email
pbsrc@mums.ac.ir
Web page address

Person responsible for scientific 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
Street address
Ibn-e-Sina Hospital, Bu-Ali Sq., Amel Blvd., Mashhad,Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
123456

Phone
+98 51 3711 2701
Fax
Email
mantegia@mums.ac.ir
Web page address

Person responsible for updating data

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
Street address
Ibn e Sina Hospital, Bu-Ali Sq, Amel Blvd, Mashhad, Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
123564
Phone
+98 51 3711 0701
Fax
Email
fahimeh.afzaljavan@gmail.com
Web page address

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