

# 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 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****Phone**

+98 51 3711 0701

**Fax****Email**

fahimeh.afzaljavan@gmail.com

**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**

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**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

123564

**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