

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Determining the effect of intravenous Ketemine on the severity of symptoms of treatment resistant depression

#### Protocol summary

##### Study aim

Determining the effect of intravenous Ketemine on the severity of symptoms of drug-resistant major depressive disorder. Introducing a low-complication and fast treatment method for the treatment of patients with refractory depression.

##### Design

The clinical trial has a control and control group that uses the rand function of Excel software for randomization

##### Settings and conduct

Sampling is done among the clients of Shahid Beheshti Hospital clinic and the drug is injected in the operating room of Ayatollah Mousavi Hospital.

##### Participants/Inclusion and exclusion criteria

Patients are selected from outpatients and hospitalized in Shahid beheshti hospital. Patients aged 25 to 60 years who were diagnosed with mojour depressive disorder based on the DSM-V criteria and did not respond to at least two antidepressants were including in the study.

##### Intervention groups

One group of patients received a single dose of intravenous Ketamine under the supervision of an anesthesiologist and cardiopulmonary monitor and the control group received a placebo (normal saline) under the same condition.

##### Main outcome variables

Severity of major depression based on the Montgomery-Asberg scale: Assessing suicidal ideation based on Beck Suicide Questionnaire

#### General information

##### Reason for update

##### Acronym

MDD

##### IRCT registration information

IRCT registration number: **IRCT20210806052096N1**

Registration date: **2022-04-09, 1401/01/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-09, 1401/01/20**

Update count: **0**

##### Registration date

2022-04-09, 1401/01/20

##### Registrant information

##### Name

Farnaz Taherkhani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3354 4001

##### Email address

taherkhanifarnaz71@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-04, 1401/01/15

##### Expected recruitment end date

2022-08-22, 1401/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Determining the effect of intravenous Ketemine on the severity of symptoms of treatment resistant depression

##### Public title

Determining the effect of Ketemine on the treatment resistant depression

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Diagnosis of major depressive disorder based on DSMV criteria Failure to respond to at least 2 antidepressants with sufficient therapeutic dose The criterion of Montgomery-Asberg at least 25

**Exclusion criteria:**

Having skull masses Having history of HTN Having history of IHD Having a recent or past psychotic disorder Consumption of recent substances Pregnancy Existence of unstable medical disease

**Age**

From **25 years** old to **60 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **62**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Clinical interviews were conducted with patients who met the inclusion criteria and a Montgomery-Asberg questionnaire was filled out by them. Next, the patients are divided into two groups; one group receiving a single dose of intravenous ketamine at a rate of 0/5 mg per kg, the other group receiving the same amount of intravenous normal saline. The drug is prepared by an anesthesiologist and is injected by a psychiatrist.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Zanjan University of Medical Sciences

**Street address**

Shahid Beheshti hospital, Ark square; Zanjan, Iran

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513615788

**Approval date**

2021-07-24, 1400/05/02

**Ethics committee reference number**

IR.ZUMS.REC.1400.150

**Health conditions studied**

1

**Description of health condition studied**

Major Depressive Disorder

**ICD-10 code**

F33.9

**ICD-10 code description**

Major depressive disorder, recurrent, unspecified

**Primary outcomes**

1

**Description**

Depression severity based on Montgomery-Asberg

**Timepoint**

Before injecting the drug-Immediately after drug injection-1 hour after drug injection-4 hour after drug injection-1 day after drug injection-3 day after drug injection-7 day after drug injection-1 month after drug injection-2 month after drug injection

**Method of measurement**

Based on Montgomery-Asberg questionnaire

**Secondary outcomes**

1

**Description**

Suicide idea

**Timepoint**

Before the drug injection-after the drug injection

**Method of measurement**

Based on the Beck questionnaire

**Intervention groups**

1

**Description**

Intervention group: Patients aged 25 to 60 years who were diagnosed with major depressive disorder based on the DSM-V criteria and did not respond to at least 2 antidepressants, receive a dose of intravenous ketamine (half a milligram per kilogram).

**Category**

Treatment - Drugs

2

**Description**

Control group: Patients aged 25 to 60 years who were diagnosed with major depressive disorder based on the DSM-V criteria and did not respond to at least 2 antidepressants, receive a dose of intravenous normal

saline (half a milligram per kilogram).

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital of Zanjan

**Full name of responsible person**

Farnaz Taherkhani

**Street address**

Shahid Beheshti hospital, Ark square; Zanjan, Iran

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**Province**

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**Postal code**

4513615788

**Phone**

+98 24 3354 4001

**Email**

Beheshti@Zums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Alireza shoghli

**Street address**

Shahid Beheshti hospital, Ark square; Zanjan, Iran

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**Email**

Beheshti@Zums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zanjan University of Medical Sciences

**Proportion provided by this source**

50

**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

**2****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Zanjan University of Medical Sciences

**Full name of responsible person**

Faramarz Dobakhti

**Street address**

Vice Chancellor for Research, University of Medical Sciences, Azadi Blvd., Zanjan, Iran

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**Province**

Zanjan

**Postal code**

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**Phone**

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**Email**

journal@zums.ac.ir

**Web page address**

<https://zums.ac.ir/journal>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for Research, Zanjan University of Medical Sciences

**Proportion provided by this source**

50

**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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Farnaz Taherkhani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Shahid Beheshti hospital, Ark square; Zanjan, Iran

**City**

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**Province**

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**Phone**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

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**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Farnaz Taherkhani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Determining the effect of intravenous Ketamine on the severity of symptoms of drug-resistant Major Depressive Disorder

**When the data will become available and for how long**

Start of access period from 1401

**To whom data/document is available**

Researchers working in academic institutions

**Under which criteria data/document could be used**

To investigate more broadly the effect of intravenous Ketamine on the treatment of depression

**From where data/document is obtainable**

Library of Zanjan University of Medical Sciences

**What processes are involved for a request to access data/document**

Visit the university library and apply for the dissertation text

**Comments**