

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)

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+98 24 3354 4001

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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

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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**

Sahid Beheshti Hospital of Zanjan

Full name of responsible person

Farnaz Taherkhani

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Shahid Beheshti hospital, Ark square; Zanjan, Iran

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

Zanjan University of Medical Sciences

Full name of responsible person

Alireza shoghli

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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

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

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

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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

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

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Person responsible for updating data

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Other areas of specialty/work

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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