Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 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 mojor 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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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
Sahid Beheshti Hospital of Zanjan

Full name of responsible person
Farnaz Taherkhani

Street address
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
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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

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

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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

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Person responsible for updating data

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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