

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of injectable ketamine with doses of 0.5 mg/kg on the control of symptoms in patients with treatment-resistant major depressive disorder: a randomized clinical trial

Protocol summary

Study aim

Investigating the effect of using a single dose of intravenous ketamine on severe and treatment-resistant depression

Design

Clinical trial without control group, without parallel group, without blinding, without randomization, single phase on 15 patients

Settings and conduct

15 patients were selected according to the inclusion criteria and were given the Hamilton and Beck tests. Then the patients are admitted to Khatam al-Anbia hospital in Shahrood and receive 0.5 mg/kg of ketamine intravenously. This study is without randomization without blinding. Then they are observed for one hour in a stable and quiet room in Khatam Al Anbia Hospital. Then, after two days, one week, one month after the injection, Hamilton and Beck tests are taken from the patients again, and the Hamilton and Beck evaluation test scores are compared before and after the injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with depressive disorder based on DSM IV_TR criteria Exclusion criteria : Respond to drug therapy or ECT - Cardiovascular problems and pregnancy

Intervention groups

The statistical population includes patients referred to Dr. Hojat Bastami's office who are suffering from treatment-resistant major depressive disorder according to DSM IV_TR criteria and will be injected with 0.5mg/kg of ketamine intravenously as a single dose.

Main outcome variables

Severity of depression Cognitive complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230618058520N1**

Registration date: **2023-07-09, 1402/04/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-09, 1402/04/18**

Update count: **0**

Registration date

2023-07-09, 1402/04/18

Registrant information

Name

Mohammad Shiroudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4452 6920

Email address

dr7sina7sh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-05, 1402/04/14

Expected recruitment end date

2023-07-11, 1402/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of injectable ketamine with doses

of 0.5 mg/kg on the control of symptoms in patients with treatment-resistant major depressive disorder: a randomized clinical trial

Public title

Investigating the effect of using ketamine on severe and treatment-resistant depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with treatment-resistant major depressive disorder based on DSM IV _ TR criteria Being in a depressive episode Failure to respond to antidepressants and shock medications and failure to control symptoms with other methods Intolerance of oral antidepressants

Exclusion criteria:

More serious psychiatric disorders: bipolar 1 and 2 - cyclothymia - psychosis - obsession - ski and affective Addiction or withdrawal from drugs Personality disorder Physical diseases such as: thyroid disorders, diabetes, hypertension, stroke, brain surgeries, etc. Response to drug treatment and control of disease symptoms with drugs Received ECT two months before starting ketamine treatment Receiving antidepressant medication one month before starting ketamine treatment Lack of consent to participate in the study Cardiovascular problems Pregnancy and breastfeeding

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrood Islamic Azad University

Street address

University Boulevard - Islamic Azad University

City

shahrood

Province

Semnan

Postal code

4318936199

Approval date

2022-09-14, 1401/06/23

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1401.042

Health conditions studied

1

Description of health condition studied

depression

ICD-10 code

F33.9

ICD-10 code description

Major depressive disorder, recurrent, unspecified

Primary outcomes

1

Description

Depression score in Beck and Hamilton test.

Timepoint

Comparison of Hamilton and Beck test results before injection, two days after injection, one week after injection, one month after injection

Method of measurement

The criterion of response to ketamine treatment is a decrease of 50% or more in Beck and Hamilton tests.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: receiving 0.5mg/kg ketamine as a single intravenous dose - Rotex medica trittau germany

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam al anbia hospital

Full name of responsible person

Yousef kolookhi

Street address

Khatam Al Anbia Hospital., Opposite Industrial University., University Blvd., Shahrood town

City

Shahrood

Province

Semnan

Postal code

3614871151

Phone

+98 23 2223 7807

Email

khatam@shahrood.ac.ir

Web page address

<https://shahrood.iau.ir/khatam-hospital/fa>

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

Vice Chancellor for Research and Technology, Shahrood Islamic Azad University

Full name of responsible person

Sahebali monafi

Street address

Khatam Al Anbia Hospital., Opposite Industrial, University Blvd., University., Shahrood town

City

Shahrood

Province

Semnan

Postal code

3614871151

Phone

+98 23 3239 4279

Email

khatam@shahrood.ac.ir

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 and Technology, Shahrood Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Mohammad shiroudi

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Shahrood, Tehran Boulevard, Shahrood Islamic Azad University

City

Shahrood

Province

Semnan

Postal code

3613773955

Phone

+98 23 3239 1796

Email

dr7sina7sh@gmail.com

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

Islamic Azad University

Full name of responsible person

Yousef kolookhi

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Shahrood, Tehran Boulevard, Shahrood Islamic Azad University

City

Shahrood

Province

Semnan

Postal code

3613773955

Phone

+98 23 3239 1796

Email

dr.yousefkolookhi.anesthezia@gmail.com

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

Islamic Azad University

Full name of responsible person

Mohammad shiroudi

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

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Postal code

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+98 23 3239 1796

Email

dr7sina7sh@gmail.com

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