

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Oct 2026

Investigating the effect of adding subcutaneous ketamine to routine treatment of treatment-resistant depressed patients

Protocol summary

Study aim

1.Determination and Comparison of mean depression scores between intervention and control groups before the intervention, at weeks 2, 4, 6, and one month after the last session. 2.Determination and Comparison of the mean number of adverse events between intervention and control groups at the same time points.

Design

A clinical trial with control group, with the parallel groups, Double-blind, randomized

Settings and conduct

in a double-blind clinical trial at Khorshid Hospital in Isfahan enrolls 52 patients with treatment-resistant major depressive disorder, who are randomly assigned to two parallel groups. Depression severity and adverse effects are evaluated at baseline, during weeks 2, 4, and 6 of treatment, and one month after the final intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Age between 60-18 years 2.Individual who have DSM-V indicators for major depression without psychotic characteristics and mania or hypomania 3.Individual who do not have an adequate response to monotherapy with antidepressants for at least two times (at least 4-6 weeks) 4.Satisfaction with participating in the study Exclusion criteria: 1.Pregnant or breastfeeding women 2.History of substance dependence or abuse in the last 3 months 3.Serious and unstable physical patients 4.Untreated hypothyroidism or hyperthyroidism 5.Current or past history of psychotic symptoms 6.History of mania or hypomania, catatonia, or depression secondary to a medical condition 7.History of hypertension 8.History of seizure disorder 9. renal failure

Intervention groups

In the intervention group, ketamine(0.5 mg/kg) is administered subcutaneously, and in the control group, normal saline is administered subcutaneously, both twice weekly for six weeks

Main outcome variables

severity of depression: side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090801002266N22**

Registration date: **2026-02-09, 1404/11/20**

Registration timing: **prospective**

Last update: **2026-02-09, 1404/11/20**

Update count: **0**

Registration date

2026-02-09, 1404/11/20

Registrant information

Name

Gholamreza Kheirabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1222 2135

Email address

kheirabadi@bsrc.mui.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-04-04, 1405/01/15

Expected recruitment end date

2027-04-04, 1406/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Investigating the effect of adding subcutaneous ketamine to routine treatment of treatment-resistant depressed patients
Public title	ketamine injection on improving treatment-resistant depression
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Age between 60-18 years Individuals who have DSM-V indicators for major depression without psychotic characteristics and mania or hypomania individuals who do not have an adequate response to monotherapy with antidepressants for at least two times (at least 4-6 weeks) Satisfaction with participating in the study Exclusion criteria: Pregnant or breastfeeding women History of substance dependence or abuse in the last 3 months Serious and unstable physical patients including liver, kidney, gastrointestinal, respiratory, cardiovascular diseases (such as ischemic heart disease), endocrine, neurological, hematological Untreated hypothyroidism or hyperthyroidism Current or past history of psychotic symptoms History of mania or hypomania, catatonia, or depression secondary to a medical condition History of hypertension History of seizure disorder Diagnosis of renal failure
Age	From 18 years old to 60 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor • Data analyser
Sample size	Target sample size: 52
Randomization (investigator's opinion)	Randomized
Randomization description	Eligible participants will be randomized using block randomization with a block size of two. Within each block, participants are ordered by national ID number. A random number table is used to determine the allocation sequence. Two possible sequences exist (A-B,B-A) , and neither participants nor investigators know which label(A orB) corresponds to ketamin or placebo . A third party who is aware of the treatment codes prepares the study medications in sealed opaque envelopes and delivers them to the research team, maintaining double blinding. This process continues until all participants have received their assigned intervention.

Blinding (investigator's opinion)	Double blinded
Blinding description	Both participants and investigators involved in outcome assessment are unaware of the treatment assignments. Study medications, labeled as A and B, are prepared by a third party who is not involved in patient evaluation. The third party is aware of the correspondence between the labels and the actual interventions (drug or placebo). The medications are placed in sealed opaque envelopes and delivered to the research team for administration. Blinding is maintained until all study outcomes have been collected.
Placebo	Used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Research Ethics Committee of School of Medicine ,Isfahan University of Medical Sciences
Street address	Isfahan University of Medical Sciences, Hezar Jerib street
City	Isfahan
Province	Isfahan
Postal code	8174673461
Approval date	2026-01-27, 1404/11/07
Ethics committee reference number	IR.MUI.MED.REC.1404.436

Health conditions studied

1	
Description of health condition studied	Treatment-Resistant Major Depressive Disorder
ICD-10 code	F33.9
ICD-10 code description	Major depressive disorder, recurrent, unspecified

Primary outcomes

1	
Description	Depression score (assessed using the HDRS)

Timepoint

Before the intervention, at week 2, week 4, and week 6 during the intervention, and one month after the last intervention session

Method of measurement

Hamilton Depressive Rating Scale (HDRS)

Secondary outcomes

1

Description

Intervention side effects

Timepoint

Before the intervention, at week 2, week 4, and week 6 during the intervention, and one month after the last intervention session

Method of measurement

checklist evaluation

Intervention groups

1

Description

Intervention group: In this group, ketamine at a dose of 0.5 mg/kg is administered subcutaneously twice weekly for six weeks, for a total of 12 injections.

Category

Treatment - Drugs

2

Description

Control group: In this group, Placebo (normal saline) is administered subcutaneously twice weekly for six weeks, for a total of 12 injections.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

Gholamreza Kheirabadi

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Ostandari street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Kheirabadi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available