

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison Between the Effect of 1 & 2 mg/kg per oral Ketamine on Control and Relapse of Depressive Symptoms in Treatment-Resistant Depressed people: A Randomized, Double-Blind Clinical Trial

Protocol summary

Study aim

Determining the effective dose of oral ketamine on Control and Relapse of Depressive Symptoms in Treatment-Resistant Depressed patients

Design

A clinical trial without the control group, with the parallel groups, Double-blind, randomized

Settings and conduct

This double-blind, randomized clinical trial will be performed at Khorshid and Al-Zahra hospitals in Isfahan. In this study, 60 patients with treatment-resistant depression will be enrolled and randomly divided into two parallel groups. Then, the severity of depression and cognitive side effects of patients during the intervention (week 2, week 4, week 6) and follow-up period (one week, one month and two months) are recorded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1- Having major depression based on DSM-V criteria of major Depressive disorder 2 - Insufficient response to treatment at least twice mono-therapy with antidepressant for at least (6-4 weeks) and sufficient dose 3- The person's desire to participate in the study
Exclusion Criteria: 1- Depression is bipolar 2- Having symptoms of psychosis

Intervention groups

For patients in the first group 2 mg/kg of ketamine as a solution in a glass of fruit juice orally and for patients in the second group 1 mg/kg of ketamine as a solution in a glass of fruit juice orally 2 times a week (For 6 weeks) will be prescribed.

Main outcome variables

severity of depression and cognitive side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090801002266N14**

Registration date: **2020-06-02, 1399/03/13**

Registration timing: **prospective**

Last update: **2020-06-02, 1399/03/13**

Update count: **0**

Registration date

2020-06-02, 1399/03/13

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

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Between the Effect of 1 & 2 mg/kg per oral Ketamine on Control and Relapse of Depressive

Symptoms in Treatment-Resistant Depressed people: A Randomized, Double-Blind Clinical Trial

Public title

Effect of oral ketamine at doses of 1 and 2 mg/kg on depression treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 60-18 years Individual who have DSM-V indicators for major depression without psychotic characteristics and mania or hypomania Individual who do not have an adequate response to monotherapy with antidepressants for at least two times (at least 4-6 weeks) No history of mania / hypomania Lack of psychotic symptoms Satisfaction with participating in the study

Exclusion criteria:

History of drug dependence or abuse in the last 3 months Pregnant or lactating women Serious and unstable physical patients including liver, kidney, gastrointestinal, respiratory, cardiovascular diseases (such as ischemic heart disease), endocrine, neurological, hematological. Taking medications that are contraindicated with ketamine is prohibited Untreated hypothyroidism or hyperthyroidism

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

60 patients selected to participate in the study were randomly assigned to one of two intervention groups. In this way, each patient chooses one of the sealed envelopes in which one of the two intervention methods is randomly placed by computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

To apply the terms of a double-blind study, 1 and 2 mg/kg doses of ketamine as a solution in a glass of juice will be prepared by the nurse (without the knowledge of the researcher), then will be marked with A and B labels, and provided to the researcher to give to the patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jerib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-03-05, 1398/12/15

Ethics committee reference number

IR.MUI.MED.REC.1398.632

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

Timepoint

The second week, the fourth week and the sixth week during the intervention and one week, one month and two months after the intervention

Method of measurement

Hamilton Depressive Rating Scale (HDRS) and Beck-2 Depression Questionnaire

Secondary outcomes

1

Description

ketamin Side effects

Timepoint

The second week, the fourth week and the sixth week during the intervention and one week, one month and two months after the intervention

Method of measurement

Intervention groups

1

Description

Intervention group: For patients in the first group, 2 mg/kg of ketamine as a solution in a glass of fruit juice orally 2 times a week (for 6 weeks) will be prescribed.

Category

Treatment - Drugs

2

Description

Intervention group: For patients in the second group, 1 mg/kg of ketamine as a solution in a glass of fruit juice orally 2 times a week (for 6 weeks) will be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Gholamreza Kheirabadi

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Sofeh boulevard

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2

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

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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?

No

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

Associate 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