Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 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 Depresive 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)

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+98 31 1222 2135

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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
Isfehan
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

checklist evaluation

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

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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
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Position
Associate professor
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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