Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

The efficacy comparison of single-dose vs. multi-dose of Ketamine on treatment-resistant depression's symptoms; a non-inferiority RCT study

Protocol summary

Study aim

Comparison of the efficacy of single dose of ketamine injection with multiple doses on reducing the symptoms of patients with refractory depression

Design

Clinical trial with two parallel groups, double-blind, randomized, performed on 30 patients, with Permuted Block Randomization using 4-block blocks and using random number table

Settings and conduct

Patients with refractory depression treated in Kargarnejad Psychiatric Hospital, in two groups; Ketamine injection as a single dose and 6 doses are evaluated. After injecting at the intervals mentioned above, in terms of the severity of depression, the Hamilton questionnaire is checked.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age: 65-18 years old; patients with major depression based on clinical interview based on DSM5 and Hamilton scale; no symptoms of psychosis in the history; patients currently on treatment with other antidepressants should not have their dose or type of medication changed in the last two months. The similarity of antidepressants received by patients in the two groups is considered; no history of addiction or substance abuse in the last 3 months; absence of serious and unstable physical illnesses. Exclusion criteria: history of one or more seizures; pregnancy or breastfeeding; bipolar disorder; a patient with suicidal thoughts who needs to be hospitalized.

Intervention groups

There are two groups of patients with refractory depression who, as adjunctive therapy, give one group of ketamine in a single dose of 0.5 mg per kilogram and the second group of ketamine in a dose of 6 doses per dose. 0.5 mg per kg is injected twice a week for up to three weeks

Main outcome variables

The main outcome variable is the Hamilton scale score. Eventually, the Hamilton Depression Scale is expected to decline during follow-up

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210125050137N1**
Registration date: **2021-02-06, 1399/11/18**
Registration timing: **prospective**

Last update: **2021-02-06, 1399/11/18**
Update count: **0**

Registration date

2021-02-06, 1399/11/18

Registrant information

Name

suroor karimipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 9111

Email address

karimipour-s@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The efficacy comparison of single-dose vs. multi-dose of Ketamine on treatment-resistant depression's symptoms; a non-inferiority RCT study

Public title
The efficacy of Ketamine on treatment-resistant depression's symptoms

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Males and females, aged 18 -65 years old DSM-V Major Depression Disorder diagnosis confirmed by The Hamilton Depression Rating Scale The patient has refractory depression, a type of major depression that has not responded to traditional treatment options and the first line of treatment and has taken at least 2 trials of antidepressant drug without sufficient response

Exclusion criteria:
Having other psychiatric illnesses other than major depression Having a history of one or more seizures for no apparent reason Pregnancy and lactation Bipolar disorder Having uncontrolled non-psychiatric illnesses, including cardiovascular disease Having a history of stimulant use during the last three months

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Investigator

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are randomized in two parallel groups by Permuted Block Randomization using (block size = 4) random number table, they receive single or multi dose ketamine .

Blinding (investigator's opinion)
Single blinded

Blinding description
Health care personnel, including physicians, patient care and follow-up, data collection and data analysis officers, have been blinded in this study. The method of drug distribution among patients is block randomization.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Kashan University of Medical Sciences

Street address
Kashan University of Medical Sciences, Ghotb Ravandi blvd.

City
Kashan

Province
Isfehan

Postal code
8715973446

Approval date
2020-12-30, 1399/10/10

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1399.194

Health conditions studied

1

Description of health condition studied
Resistant depression

ICD-10 code
F33.9

ICD-10 code description
Major depressive disorder, recurrent, unspecified

Primary outcomes

1

Description
Depression score based on Hamilton scale

Timepoint
Monthly

Method of measurement
Hamilton questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the first intervention group: patients are treated with a single dose of ketamine. In this group, ketamine is received only once, 50 cc of normal saline, which contains 0.5 mg per kg of body weight of ketamine hydrochloride, by pump or micro set within 40 minutes

intravenously. Vial ketamine 10cc / 500 mg used by the company Rotex Medica is German.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group 2: Patients with multiple doses twice a week for up to 3 weeks receive 50 cc of normal saline containing 0.5 mg per kg body weight of ketamine hydrochloride intravenously by pump or micro set for 40 minutes. Ketamine 10cc / 500mg is used by the German company Rotex Medica.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kargarnejad Psychiatric Hospital, Kashan

Full name of responsible person

Suroor Karimipour

Street address

Qutb Ravandi Boulevard, end of Parastar Boulevard

City

Kashan

Province

Isfehan

Postal code

8715973446

Phone

+98 31 5554 9111

Email

karimipour-s@kaums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafshe

Street address

Qutb Ravandi Boulevard, end of Parastar Boulevard

City

Kashan

Province

Isfehan

Postal code

8731753153

Phone

+98 31 5554 2999

Fax

+98 31 5557 5057

Email

banafshe57@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

10

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

Kashan University of Medical Sciences

Full name of responsible person

Afshin Ahmadvand

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Qutb Ravandi Boulevard, end of Nurse Boulevardvandi blvd.

City

Kashan

Province

Isfehan

Postal code

8715973446

Phone

+98 31 5554 9111

Email

afshin.ahmadvand@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zahra Sepehrmanesh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Qutb Ravandi Boulevard, end of Nurse Boulevard

City
Kashan

Province
Isfehan

Postal code
8715973446

Phone
+98 31 5554 9111

Email
z.sepehrmanesh @gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Suroor Karimipour

Position
Psychiatric Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Qutb Ravandi Boulevard, end of Nurse Boulevard

City
Kashan

Province
Isfehan

Postal code
8715973446

Phone
+98 31 5554 9111

Email
karimipour-s@kaums.ac.ir

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
The information of the study participants is confidential

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Participants in the Depression Resistant Patients Project are referred to Kargarnejad Hospital

When the data will become available and for how long
After one year

To whom data/document is available
University professors and assistants

Under which criteria data/document could be used
Evaluate the effects of treatment

From where data/document is obtainable
Research Center of Kashan University Vice Chancellor for Research

What processes are involved for a request to access data/document
Letter from the Vice Chancellor for Student Research and with the approval of the research supervisor

Comments