

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Oct 2026

The Permanent Effects of double doses of intravenous Es-Ketamine on suicidal thoughts and behaviors in the Major depressive disorder: a randomized double-blind placebo-controlled clinical trial study

Protocol summary

Study aim

To compare suicidal ideation and behaviors between the case and control groups after 24 hours, 7 days, 10 and 14 days post infusion. To compare characteristics including sex, age of onset, duration and episodes and family history of a disease. To compare symptoms of Major depressive disorder before and 2 weeks after Es-Ketamine or Midazolam infusion.

Design

A randomized double blind placebo controlled clinical trial designed for 90 patients enrolled between May 2019 and March 2020

Settings and conduct

All patients will receive a dose of 0.5mg/Kg of intravenous Es-Ketamine in day 1. Then half of them will receive a dose of 0.045mg/Kg intravenous Midazolam and other will receive a dose of 0.5mg/Kg of Es-Ketamine in day 14. Drugs will dilute in 100cc normal saline and infuse over 45 minutes by anesthetics and under anesthesiologist supervision. Suicidal ideation and behavior will be measured using the Beck Scale for Suicide Ideation (BSSI) during the follow-up periods. The evaluating researcher and the patients will be unaware of the treatment protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are admitted in Hafez and Ebne sina hospitals, Shiraz, with complaints of suicidal ideas and with major depressive disorder, age between 18 and 65 years old. Exclusion criteria: positive history of alcohol or substance abuse during the past 6 months; mood disorders due to another medical condition; pregnancy or lactation; positive history of Ketamine abuse; psychosis; unstable medical conditions; hypersensitivity to Ketamine or Midazolam and positive history of use of psychotropic agents or drugs like Corticosteroids.

Intervention groups

Infusion of Es-Ketamine Hydrochloride in day 1 and 14 in intervention group and infusion of Es-Ketamine Hydrochloride in day 1 and Midazolam in day 14 in control group.

Main outcome variables

Suicidal idea and behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160105025859N1**

Registration date: **2019-06-08, 1398/03/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-08, 1398/03/18**

Update count: **0**

Registration date

2019-06-08, 1398/03/18

Registrant information

Name

Laaya Ahmadzadeh

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-20, 1398/02/30

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Permanent Effects of double doses of intravenous Es-Ketamine on suicidal thoughts and behaviors in the Major depressive disorder: a randomized double-blind placebo-controlled clinical trial study

Public title

evaluation of s-ketamine effects on reducing suicidal thoughts and behaviors in major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

This clinical trial study will be conducted in Ebne Sina and Hafez Hospital, Shiraz, Iran and all patients who are admitted to our medical care center during a one year period with complaints of suicidal ideas and with a diagnosis of DSM-5 major depressive disorder (MDD),

Exclusion criteria:

Those who have a positive history of alcohol or substance abuse during the past 6 months mood disorders due to any medical conditions pregnancy or lactation those with a positive history of ketamine abuse those with symptoms of psychosis unstable medical conditions with hypersensitivity to ketamine positive history of use of psychotropic agents or drugs like corticosteroids

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet our inclusion criteria will be randomly allocated into 2 groups using a permuted block randomization method (using blocks of two).

Blinding (investigator's opinion)

Double blinded

Blinding description

The evaluating researcher and the patients will be unaware of the treatment protocol. All treatment

modalities will be carried out by an independent medical professional. All patients will be followed by a single observer who will solely be responsible for the evaluation of outcomes. This investigator will be unaware of patient treatment and grouping. Patients will be referred to the investigator for evaluation after receiving planned intervention and any information on the intervention program prior to the visit will be controlled by a clinical trial nurse who will be responsible for control of data related to the intervention program.

Placebo

Used

Assignment

Parallel

Other design features

Patients included in the study were all under treatment with SSRIs(selective serotonin reuptake inhibitors) class and if another medication modalities that have confirmed antidepressant effect (such as lithium or ECT) were considered by physician to treat suicidal ideation, they excluded from the study.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz university of medical sciences

Street address

Zand Avn.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-02-19, 1397/11/30

Ethics committee reference number

IR.SUMS.MED.REC.1397.536

Health conditions studied**1****Description of health condition studied**

Suicidal thoughts and behaviors

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Suicidal thoughts and behaviors

Timepoint

Patients will be evaluated at baseline (8 hours before infusion), 24 hours, 7 and 10 days and two weeks after each infusions of Es-Ketamine or Midazolam in both groups.

Method of measurement

The Beck Scale for Suicide Ideation (BSSI)

Secondary outcomes

1

Description

Es-Ketamine administration will reduce symptoms of patients with Major Depressive disorder 2weeks post infusion.

Timepoint

before and 2 weeks after Es-Ketamine or Midazolam infusion.

Method of measurement

Hamilton Rating Scale for Depression (HRSD)

Intervention groups

1

Description

Intervention group: Those diagnosed with major depressive disorders who aside to their routine and standard treatment will receive a dose of 0.5mg/Kg of Es-Ketamine Hydrochloride from KETAMIN ROTEXMEDICA injection 50mg/ml, 10 ml, diluted in 100 cc normal saline, during 45 minutes in day 1 and 14.

Category

Treatment - Drugs

2

Description

Control group: Those diagnosed with major depressive disorder who will receive a dose of 0.5mg/Kg of intravenous Es-ketamin in day 1 and a dose of 0.045mg/Kg intravenous MIDAZOLAM ABURIHAN ampul 5mg/ml,1ml, in day 14. all medications will dilute in 100cc normal saline and infuse during 45 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebne sina hospital

Full name of responsible person

Laya Ahmadzade

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

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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

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Laya Ahmadzade

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

results of the main consequences will share.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

share with Scientific institutions

Under which criteria data/document could be used

for any other researches

From where data/document is obtainable

Contact with samane7rahimi86@yahoo.com

What processes are involved for a request to access data/document

Data will share within 3 months after contact via E-mail

Comments