Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 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- Ketamin in day 1. Then half of them will receive a dose of 0.045mg/Kg intravenous Midazolaand 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
Street address
Hafez Ave.
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7134814336
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2

Recruitment center
Name of recruitment center
Hafez hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Yunes Ghasemi
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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

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Resident assistant
Latest degree
Medical doctor
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Email
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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