Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

Assessment of effect of intravenous ketamine in suicidal ideas among patients with major depressive disorder in comparison with control group

Protocol summary

Summary

Assessment of effect of intravenous ketamine in suicidal ideas among patients with major depressive disorder in comparison with control group Objectives: Effect of intervenous ketamine in suicidal ideation in patients with major depressive disorder is demonstrated as a change in suicidal thoughts in comparison with control group. Aim: decrease in suicidal thoughts Design: double blind randomized clinical trial Setting and conduct: 60 patients suffering from major depression who have been reffered to Ebne Sina hospital will be included in the study. The patients should not use any drug, in the previous month. In order of referral, the patients will be divided into 2 groups A & B using a random number table, which is done by a psychiatrist. The patients are unaware about the treatments. In group A, 0.5 mg/kg Ketamine diluted in 500 cc normal saline will be infused in 30 minutes and in group B 500 cc normal saline without ketamine will be infused. All patients will be in their room steady & calm for 1 hour the vital signs and drug side effects will be checked 2, 24 & 72 hours and 7 days after injection. The criteria will be checked again the person who assess the criteria is also blind of the drug injected to the patient Statistical analysis: the findings will be analysed by paired t test with SPSS version 21 Major Inclusion and Exclusion criteria: Inclusion criteria: depression diagnosis due to DSM IV criteria; benign major depression episode; suicidal thoughts; no use of antidepression drugs in last month; age above 18 Exclusion criteria: bipolar disorder type 1 & 2; cyclothymia; psychosis having other disorder of 1or 2 axis simultaneusly; drug addiction or withdrawal; medical disease which causes depression; pregnancy; breast feeding; cardiovascular disease history Intervention: intravenous ketamine main outcome measures (variables) suicidal thoghts and quantity of deprssion

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015030921397N1**
Registration date: **2015-07-17, 1394/04/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-17, 1394/04/26

Registrant information

Name

Farah Moayedi

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 76 3334 7897

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hormozgan University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessment of effect of intravenous ketamine in suicidal ideas among patients with major depressive disorder in comparison with control group

Public title
Assessment of effect of intravenous ketamine in suicidal ideas among patients with major depressive disorder in comparison with control group

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: depression diagnosis due to DSM IV criteria; benign major depression episode; suicidal thoughts; no use of antidepression drugs in last month; age above 18 Exclusion criteria: bipolar disorder type 1 & 2; cyclothymia; psychosis having other disorder of 1or 2 axis simultaneusly; drug addiction or withdrawal; medical disease which causes depression; pregnancy; breast feeding; cardiovascular disease history

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization is done by simple randomization using random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics comittee of Hormozgan University of Medical Sciences

Street address
Shahid Chamran Boulevard

City
Bandar Abbas

Postal code
7919915519

Approval date
2015-01-27, 1393/11/07

Ethics committee reference number
4/HEC-93-11-7

Health conditions studied

1

Description of health condition studied
Suicide attempt- Depression

ICD-10 code
z91.5, F3

ICD-10 code description
Severe depressive episode without psychotic symptoms, Personal history of self-harm

Primary outcomes

1

Description
The effect of suicidal thoughts

Timepoint
2, 24, 72 hours and 7 day after drug injection

Method of measurement
Beck suicidal ideation questionnaire

Secondary outcomes

1

Description
quantity of depression

Timepoint
2, 24, 72 hours and 7days after drug injectinon

Method of measurement
Beck depression questionaire

Intervention groups

1

Description
Intervention group: 0.5 mg/kg IV ketamine/30 min and the patient is monitored for 2, 24, 72 hrs and 7 days for adverse drug reactions.

Category
Treatment - Drugs

2

Description
Control group: 500 cc IV normal saline as placebo

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ebne Sina Psychiatric Hospital
Full name of responsible person
Farah Moayedi
Street address
Emam khomeini Boulevard, Bandar Abbas
City
Bandar Abbas

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Hormozgan University of Medical Sciences
Full name of responsible person
Abdol azim Nejati zadeh
Street address
Shahid Mohammadi Hospital, Emam Khomeini Boulvard
City
Bandar Abbas
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Hormozgan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty