

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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 intravenous 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 referred 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 antidepressant drugs in last month; age above 18 Exclusion criteria: bipolar disorder type 1 & 2; cyclothymia; psychosis having other disorder of 1 or 2 axis simultaneously; drug addiction or withdrawal; medical disease which causes depression; pregnancy; breast feeding; cardiovascular disease history Intervention: intravenous ketamine main outcome measures (variables) suicidal thoughts and quantity of depression

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)

Phone

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Email address

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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 antidepressant drugs in last month; age above 18 Exclusion criteria: bipolar disorder type 1 & 2; cyclothymia; psychosis having other disorder of 1 or 2 axis simultaneously; 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 committee 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 injection

Method of measurement

Beck depression questionnaire

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

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Web page address

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

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Shahid Mohammadi Hospital, Emam Khomeini
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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

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

Contact

Name of organization / entity

Hormozgan University Medical Sciences

Full name of responsible person

Farah Moayedi

Position

Psychiatrist

Other areas of specialty/work

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Intern

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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