Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

Comparison of anti-depressant effect of oral ketamine, intramuscular ketamine and electroconvulsive therapy in the patients with major depressive disorder

Protocol summary

Study aim
Determining and comparison of anti-depressant effect of oral ketamine, intramuscular ketamine and electroconvulsive therapy in the patients with major depressive disorder

Design
A pilot study with a parallel group design of 45 patients, enrolled between October and November 2018 through three weeks, and followed for one month.

Settings and conduct
The patients are divided into three 15 individual groups which receive electro convulsive therapy, 1mg/kg oral ketamine and 0.5 mg/kg intramuscular ketamine through 3 weeks in 6-9 sessions. the 17 items Hamilton depression scale(17-HDS) and beck scale for suicidal ideation (BSSI) will be assessed and compared between groups in specific intervals and one month after last intervention. also the satisfaction of each group will be assessed with a questionnaire and compared between groups.

Participants/Inclusion and exclusion criteria
Patients with major depressive disorder candidate for electroconvulsive therapy

Intervention groups
The severe major depressive patients taking oral ketamine, the severe major depressive patients taking intramuscular ketamine, the severe major depressive patients receiving electrocconvusive therapy

Main outcome variables
Determination of anti depressant effect of oral ketamine, intramuscular ketamine in comparison with electroconvulsive therapy

General information

Reason for update
Given the low power of the study; and that no similar study has been conducted so far, we would like to introduce this study as a pilot study.

Acronym

IRCT registration information
IRCT registration number: **IRCT20090801002266N8**
Registration date: **2018-10-31, 1397/08/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-10, 1398/12/20**
Update count: **1**

Registration date
2018-10-31, 1397/08/09

Registrant information

Name
Gholamreza Kheirabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 1222 2135

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-12, 1397/07/20

Expected recruitment end date
2018-12-11, 1397/09/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of anti-depressant effect of oral ketamine, intramuscular ketamine and electroconvulsive therapy in the patients with major depressive disorder

Public title
Antidepressant effect of ketamine

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Major depressive patients based on DSM 5 criteria candidate for electro convulsive therapy Age between 18-70 years old Informed consent form obtained

Exclusion criteria:
Drug side effects which discontinuation is necessary Patient`s disagreement to stay in study Deterioration of patient`s symptoms Not to respond after 4 intervention sessions. Drug sensitivity Severe or active hepatic renal cardiac urological disease Substance abuse Previous manic or hypo manic episode Catatonia Secondary depression due to another medical conditions History of psychosis

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The selected 45 cases in this study, will be divided in three intervention groups as block randomization, with sealed envelops numbered 1 to 45 in which there is an intervention method, that is randomly selected with computer software.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study the patients divides into three 15 individual groups which receive electro convulsive therapy, 1mg/kg oral ketamine and 0.5 mg/kg intramuscular ketamine through 3 weeks in 6-9 sessions. the 17 items Hamilton depression scale(17-HDS) and beck scale for suicidal ideation (BSSI) will be assessed and compared between groups in specific intervals and one month after last intervention. also the satisfaction of each group will be assessed with a questionnaire and compared between groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics commitee of isfahan university of medical science

Street address
Behavioal science research center, Noor hospital, Ostandari street, Isfahan, Iran

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Isfahan

Province
Isfehan

Postal code
8145831451

Approval date
2017-12-21, 1396/09/30

Ethics committee reference number
IR.MUI.REC.1396.3.956

Health conditions studied

1

Description of health condition studied
Major depressive disorder

ICD-10 code
F33.2

ICD-10 code description
Major depressive disorder, recurrent severe without psychotic features

Primary outcomes

1

Description
Depression score in hamilton depression scale

Timepoint
Before intervention, 24 hours, one week, two weeks, three weeks, four weeks and eight weeks after begining the intervention

Method of measurement
Hamilton depression scale-17 items

Secondary outcomes

1

Description
Suicidal scores in beck scale for suicidal ideation

Timepoint
Before intervention, 24 hours, one week, two weeks, three weeks, four weeks and eight weeks after begining the intervention

Method of measurement

Beck scale for sicidal ideation

Intervention groups

1

Description
First intervention group: intra muscular ketamine, NMDA antagonist, 0.5mg/kg dosage, 500 mg vial, rotex medica factory in Germany, 6-9 injection through 3weeks
Category
Treatment - Drugs

2

Description
Second intervention group: intra muscular ketamine, NMDA antagonist, 1mg/kg dosage, 500 mg vial, rotex medica factory in Germany, 6-9 prescription through 3 weeks in which the injectable ketamine will be added to juice and will be taken orally.
Category
Treatment - Drugs

3

Description
Third intervention group: the bilateral electroconvulsive therapy group that begin with 25mC after short anesthesia in 6-9 sessions through three weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Noor Hospital
Full name of responsible person
Gholamreza Kheirabadi
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Behavioral sciences research center, Noor hospital, Ostandari Street, Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
Street address
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Kheirabadi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Associate professor

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Person responsible for updating data

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Full name of responsible person

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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

there is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available