

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 electroconvulsive 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)

Phone

+98 31 1222 2135

Email address

kheirabadi@bsrc.mui.ac.ir

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 envelopes 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 committee of isfahan university of medical science

Street address

Behavioral science research center, Noor hospital, Ostandari street, Isfahan, Iran

City

Isfahan

Province

Isfahan

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 beginning 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 beginning the intervention

Method of measurement

Beck scale for suicidal 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

Street address

Behavioral sciences research center, Noor hospital, Ostandari Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8145831451

Phone

+98 31 1222 2135

Fax

+98 31 1222 2135

Email

kheirabadi@bsrc.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Isfahan University of Medical Sciences, Hezarjerib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

reasearch@mui.ac.ir

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

Street address

Behavioral science research center, noor hospital, ostandari street, isfahan, iran

City

Isfahan

Province

Isfahan

Postal code

8145831451

Phone

+98 31 3222 2135

Email

kheirabadi@bsrc.mui.ac.ir

Person responsible for scientific 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

Street address

Behavioral sciences research center, Noor hospital,
Ostandari Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8145831451

Phone

+98 31 3222 2135

Email

kheirabadi@bsrc.mui.ac.ir

Person responsible for updating data

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

Street address

Behavioral sciences research center, Noor hospital,
Ostandari Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8145831451

Phone

+98 31 3222 2135

Email

kheirabadi@bsrc.mui.ac.ir

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