Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Evaluating Lamotrigine in relapse prevention following intravenous ketamine in 18-65 years old patients with treatment resistant depression in ziaeian hospital in 2013-2014 in a pilot study

Protocol summary

Summary

The aims of this study are to evaluate the effect of intravenous infusion of ketamine in response to treatment of treatment-resistant depression and the effect of oral Lamotrigine maintenance therapy after intravenous infusion of ketamine. The study was designed as a randomized, double blind, placebo-controlled, single-center, and phase II clinical trial. 30 patients will choose from 18 to 65 years old patients, who admitted to the Psychiatric Clinic of Ziaeian hospital based on inclusion criteria. Inclusion criteria are: 18 to 65 years old patients with treatment resistant depression, the current episode of depression lasting at least 4 to 6 weeks, be at least at the second stage of TRD. And also HDRS score of 21 with Hamilton scoring is higher or equal to 18. Exclusion criteria are: Patients with depression secondary to medical illness, drug or alcohol abuse, pregnant or lactating women, patients with medical or psychiatric comorbidities, patients with a known history of intolerance or sensitivity to ketamine, patients at serious risk of suicide and homicide, patients with obstructive sleep apnea or a history of difficult airway management in previous anesthesia, patients treated with MAO irreversible inhibitors during the two weeks prior to the intervention, and in general, patients with clearly abnormal findings in laboratory tests, physical examination, or electrocardiogram. The diagnosis is based on interviews by two psychiatrists on DSMIV criteria. The depression levels will determine based on Hamilton Depression Inventory. Consent from clients who have volunteered to participate in the research will done, the patient will continue their previous medications. After arriving at the operating room, patients will receive standard monitoring include pulse oxymetry, ECG, NIBP. An IV line number 20 will be placed. For patients, 0 / 5mg / kg ketamine based on ideal body weight (IBW) will infuse over 40 minutes. Patients will be monitored for 24 hours in the ward. Patients will complete the Hamilton questionnaire 60 minutes before the intervention, and also, 120 min, 240 min and 24 and 72 hours after intervention. Patients who responding in this stage while continue previous medications will randomly divide into two groups (Intervention/Control). The intervention group will be treated with oral Lamotrigine (25 mg daily for first and second week, 50 mg daily for third and fourth week, 100 mg daily for fifth week and 200 mg daily for the sixth week). Control group will receive placebo for 6 weeks. Both groups will complete Hamilton questionnaire every week up to 6 weeks. Then two intervention and control groups will be compared in terms of scoring.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013110415276N1**
Registration date: **2014-09-26, 1393/07/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-26, 1393/07/04

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete
Funding source
institution

Expected recruitment start date
2014-09-23, 1393/07/01
Expected recruitment end date
2015-03-20, 1393/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating Lamotrigine in relapse prevention following intravenous ketamine in 18-65 years old patients with treatment resistant depression in ziaeian hospital in 2013-2014 in a pilot study

Public title
Effect of lamotrigine in relapse prevention following intravenous ketamine in depression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 1- patients 18 to 65 years 2- be able to understand the intervention 3- submit their written consent. 4- Being infected with treatment-resistant depression diagnosed by a psychiatrist. 5- current depressive episode lasting 4 to 6 weeks. 6- Be at least at the second stage of TRD (Failure to respond to antidepressant treatment with 2 drug families in the current episode based on Antidepressant Treatment History Form). 7- HDRS score of 21 with Hamilton scoring is higher or equal to 18. 8- Women of reproductive age have negative βHCG and use reliable method of contraception during the study period. Exclusion criteria: 1- patients with depression secondary to medical illness, drug or alcohol abuser (except nicotine and caffeine) according to the criteria of DSMIV. 2- pregnant or lactating women. 3- patients with a history of seizure disorder other than epilepsy and fever. 4- patients with a known history of intolerance or sensitivity to ketamine and lamotrigine. 5- patients with diagnosis of schizophrenia and bipolar disorder, and psychotic signs. 6- patients with Tourette syndrome, autism and mental retardation. 7- patients at serious risk of suicide and homicide. 8- patients with obstructive sleep apnea or a history of difficult airway management in previous anesthesia. 9- patients treated with MAO irreversible inhibitors during the two weeks prior to the intervention. 10- patients with clinical and laboratory evidence of medical disorders, such as impaired hepatic or renal function, coronary disease, cerebrovascular disease, viral hepatitis B and C, acquired immunodeficiency syndrome, diabetes mellitus, uncontrolled hypertension, unmodified hypothyroidism or hyperthyroidism, neurological , immunological or hematologic disorders and in general, patients with clearly abnormal findings in laboratory tests, physical examination, or electrocardiogram.

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
6th floor, central building of university, Qods st, Keshavarz blv
City
Tehran
Postal code
Approval date
2014-08-31, 1393/06/09
Ethics committee reference number
۱۳۰/۱۱۴۵/۹۳/ص

Health conditions studied

1

Description of health condition studied
Treatment – Resistant Depression
ICD-10 code
F32.1 & F3
ICD-10 code description
Severe depressive episode without psychotic symptoms and Moderate depressive episode

Primary outcomes

1

Description
Depression rating scale
Timepoint
60 minute before the intervention,120 minute,240 minute, 24 and 72 hours after intervention. then once per week up to 6 weeks
Method of measurement
Hamilton Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description
Infusion of intravenous Ketamine vials 0/5 mg per Kg of ideal body weight during the 40-minute . oral Lamotrigine tablet 25 mg daily for first and second week,then 50 mg daily for third and fourth week,then 100 mg daily for fifth week and then 200 mg daily for the sixth week for intervention group.
Category
Treatment - Drugs

2

Description
Infusion of intravenous Ketamine vials 0/5 mg per Kg of ideal body weight during the 40-minute . oral placebo tablet daily up to 6 week for control group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ziaeian Hospital
Full name of responsible person
Dr. Mohammad Effatpanah
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Ziaeian Hospital. Opposite Municipality. Abouzar St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Dr. Masoud Yunesian
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6th floor, Central building of university, Qods st, Keshavarz blv
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Tehran
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, Tehran 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
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Position
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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