

# 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 ziaieian 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 Ziaieian 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

###### Name

Mohammad Effatpanah

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5574 5975

###### Email address

m-effatpanah@tums.ac.ir

**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 ziaeiian 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  $\beta$ HCG 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 &amp; 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

#### Street address

Ziaeian Hospital. Opposite Municipality. Abouzar St.

#### City

Tehran

## 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

### Street address

6th floor, Central building of university, Qods st, Keshavarz blv

### City

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

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Mohammad Effatpanah

#### Position

Fellowship in Child & Adolescent Psychiatry \_  
Assistant professor

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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Tehran University of Medical Sciences, International Campus

**Full name of responsible person**

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**Position**

Medical student

**Other areas of specialty/work**

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Student Research Center of International campus.  
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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*