Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

Comparison the effect of electroconvulsive therapy and intravenous infusion of ketamine on control and relapse of depressive symptoms in depressive cases who are candidate of electro convulsive therapy

Protocol summary

Summary

In a single blind randomized clinical trial, 40 major depressive cases who referred to ECT selecting with a simple randomization method and will be assigned to 2 case and control grope (20 person in each group). Control group receives 3 time/week bi-temporal ECT until complete symptom remission by a psychiatrist and anesthesiologist (as a routine of treatment with ECT program) who are not in research team. Intervention group receives 3time/ week slow infusion of 0.5mg/kg ketamine until complete symptom remission with direct supervision of an anesthesiologist. Severity of major depressive symptoms will be evaluated in both group using Hamilton Depressive Rating Scale (HDRS) prior to intervention, prior to each intervention session, one week, 1, 2 and 3 month after final intervention session by a psychiatrist who is blind to interventions. Cognitive function evaluate using Adult Wechsler Memory Scale, both group will be evaluated periodically for other potential side effects by a psychiatric resident who is blind to interventions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104092266N2**
Registration date: **2011-06-08, 1390/03/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-06-08, 1390/03/18

Registrant information

Name

Gholamreza Kheirabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2011-06-22, 1390/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of electroconvulsive therapy and intravenous infusion of ketamine on control and relapse of depressive symptoms in depressive cases who are candidate of electro convulsive therapy

Public title

ketamine role in depression treatment

Purpose

Treatment

Inclusion/Exclusion criteria

IInclusion Criteria: Known case of major depressive disorder without psychotic feature based on DSM IV-TR who Referred to ECT by a psychiatrist; age between 20-50 years; signing the consent form. Exclusion Criteria:

History of psychosis or being psychotic; substance abuse during recent 3 months; breast feeding mothers; having medical incapacitating disease such as: renal, hepatic, gastro intestinal, cardiovascular, endocrine, neurologic and hematologic disease based on history and clinical and Para clinical evaluations; history of seizure with unknown origin; uncontrolled hypo or hyper thyroidism ; simultaneous another psychiatric interventions

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
ketamin and depression

Secondary trial Id
389328

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jerib Avey, Isfahan, Iran

City
Isfahan

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
389328

Health conditions studied

1

Description of health condition studied
Major Depression

ICD-10 code
F32.2

ICD-10 code description

Primary outcomes

1

Description
Severity of major depressive symptoms

Timepoint
prior to each intervention session, one week, 1,2 and 3 month afer intervention

Method of measurement
structured interviewe based on Hamilton Depressive Rating Scale

Secondary outcomes

1

Description
Cognitive Side effects

Timepoint
Prior to intervention, one week and one month after intervention

Method of measurement
Adult Wechsler Memory Scal

Intervention groups

1

Description
Intervention group:receives 3time/ week slow infusion of 0.5mg/kg ketamine until complete symptom remission with direct supervision of an anesthesiologist

Category
Treatment - Drugs

2

Description
Control group: receives 3 time/week bi-temporal ECT until complete symptom remission by a psychiatrist and anesthesiologist

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Psychiatric Department, Khorshid hospital, Isfahan University of Medical Sciences

Full name of responsible person

Dr Abbas Attari

Street address

City

Behavioral Sciences Reaserh Center,Khorshid hospital

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Mohammad Sabz Ghabaei

Street address

Vece chancellor for Reaserch,Isfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan 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

Behavioral Sciences Research Center, Isfahan University of Medical Sciences

Full name of responsible person

Dr Gholam Reza Kheirabadi

Position

Psychiatrist/ Assistant professor

Other areas of specialty/work

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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