Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

• Anti depressant effect of Ketamin versus Thiopental Na for ECT in major depression disorder patients

Protocol summary

Summary

The main objective of this clinical trial is assessing therapeutic effects of Ketamin on patients with major depression disorder (MDD) who undergo Electroconvulsive therapy (ECT) under general anesthesia. This is a double blind study performing in Shahid Beheshti Psychiatric Hospital. Inclusion criteria are: all patients with MDD subjected to ECT, age 18 – 50. Exclusion criteria: high intracranial pressure (ICP), intracranial tumors, high blood pressure, history of ischemic heart diseases, aneurism in main vessels. Sixty patients with MDD who need ECT will be divided into two groups of 30 ones by means of random numbers table. In first group, Ketamin is administered for inducing anesthesia and in second group Sodium Thiopental is used. In both groups, a psychiatrist who is blind to administered medicine evaluates the patients by The Hamilton Rating Scale for Depression (HRSD) before and after ECT. Other items which will be evaluated are: severity and duration of seizure, recovery time, and blood pressure and heart rate changes. After every two sessions of ECT, HRSD will be evaluated by a psychiatrist who is blind to administered medication, and achieved values of both groups will be compared by statistical tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208159585N2**
Registration date: **2013-02-07, 1391/11/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-02-07, 1391/11/19

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Kerman University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

• Anti depressant effect of Ketamin versus Thiopental Na for ECT in major depression disorder patients

Public title

Assessment of therapeutic effects of Ketamin in treatment of major depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients with MDD subjected to ECT who is validated by a psychiatric physician, age 18 – 50. Exclusion criteria: Ketamin contraindication, open eye

injuries with high IOP, high ICP, intracranial tumors, tachycardia, high blood pressure, history of ischemic heart diseases, aneurism in main vessels, alcohol and drug consumption within last 3 months, history of Intracranial Hemorrhage(ICH),cardiovascular diseases, unstable medical illnesses, pregnancy, patients older or younger than mentioned age, weight more than 90Kg,allergy to Ketamin, hypo and hyperthyroidism, other mental disorders coexisted with MDD such as dementia and bipolar disorder, patients with pacemakers, patients without informed consent or their family are unreliable.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This is a double blind clinical trial on 60 patients who undergo Electroconvulsive therapy (ECT). All the patients will sign informed consent but they are blind to the administered medicine. The patients will be divided into two groups of 30 ones by means of random numbers table. A resident of anesthesiology injects the medicine; however the anesthesia technician who controls and records the vital signs and severity of convulsion, and the psychologist who evaluates the patient are unaware of the medication.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Jomhoori Boulevard

City
Kerman

Postal code

Approval date
2012-05-19, 1391/02/30

Ethics committee reference number
k/91/61

Health conditions studied

1

Description of health condition studied
major depression

ICD-10 code
f33.2

ICD-10 code description
Recurrent depressive disorder, current episode severe without psychotic symptoms

2

Description of health condition studied
Major depression

ICD-10 code
f32.2

ICD-10 code description
Severe depressive episode without psychotic symptoms

Primary outcomes

1

Description
severity of depression

Timepoint
before starting, after second, 4th, 6th session of ECT

Method of measurement
Hamilton questionnaire

Secondary outcomes

1

Description
blood pressure and heart rate

Timepoint
before induction, after ECT, 5, 10, 15 minutes later

Method of measurement
electronic monitoring device

2

Description
duration of seizure

Timepoint
every session

Method of measurement
second

3

Description
recovery time

Timepoint
after administration of anesthetic drugs until the

patient's consciousness

Method of measurement

minute

Intervention groups

1

Description

Intervention: Ketamin (50 mg per ml, made by ROTEXMEDICA/Germany) 0.5_1mg/kg, administering stat and IV.

Category

Treatment - Drugs

2

Description

Control: Thiopental Na (50 mg per ml, made by Nani Pharmaceuticals Pvt.Ltd) 3 mg/kg, administering stat and IV.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Psychiatric Hospital

Full name of responsible person

Street address

Jomhori Boulevard

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Hassani

Street address

Tahmasbabad Square, Ebnesina Street

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Kerman

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 of Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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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