Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of Naltrexone versus placebo on memory deficit followed by Electroconvulsive therapy in depressed patients: A double blind clinical trial

Protocol summary

Summary

Electroconvulsive therapy (ECT) is famously known as a treatment for psychiatric disorders as in particular depressive illness. In this regard, memory impairments have always been a focus of concern. Various pharmacological agents have been studied to assess their possible effect in attenuation of memory and other cognitive adverse effects. In this randomized placebo-controlled study 40 depressed patients aged 18 to 65, candidate for six ECT sessions, who met DSM IV criteria for Major Depressive Episode were eligible. The effect of capsule Naltrexone versus placebo which is prescribed the night before ECT sessions , in memory deficit induced by ECT is being assessed. The Whechsler memory questionnaire will be filled out by face to face interview with patients, at the day before ECT sessions, two weeks, one month and three months after ECT sessions. Hamiltone Depression Rating Scale will also be filled out before and 3 months after ECT session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060628309N1**
Registration date: **2016-09-02, 1395/06/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-02, 1395/06/12

Registrant information

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Somayeh Motazedian
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Fasa University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Naltrexone versus placebo on memory deficit followed by Electroconvulsive therapy in depressed patients: A double blind clinical trial

Public title

The effect of Naltrexone on memory deficit induced by Electroconvulsive therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : aged 18 to 65 years; major depression or bipolar depression disorder patients based on DSM4 criteria; indicated for ECT Exclusion criteria: affected by a prominent medical condition; diagnosed with

schizophrenia or mania; a history of ECT in the last 6 month; recent opioid use

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: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Random number Table

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti Medical University

Street address
Shahid Beheshti Medical University, Tehran

City
Tehran

Postal code

Approval date
2011-09-24, 1390/07/02

Ethics committee reference number
9169

Health conditions studied

1

Description of health condition studied
Depressive Episode

ICD-10 code
F32

ICD-10 code description
Depressive episode

2

Description of health condition studied
Memory deficit induced by electroconvulsive therapy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Memory deficit

Timepoint
At the day before ECT sessions, two weeks, one month and three months after ECT sessions

Method of measurement
Wechsler memory test

Secondary outcomes

1

Description
Depression severity

Timepoint
Before and 3 months after ECT session

Method of measurement
Hamilton Depression Questionair

Intervention groups

1

Description
Intervention Group: Naltrexone cap 50 mg , The night before ECT session

Category
Treatment - Drugs

2

Description
Control Group: Placebo Capsule The afternoon before ECT session

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Psychiatry, Imam Hossein Hospital

Full name of responsible person

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Shahid Beheshti University of Medical Sciences
Full name of responsible person
Alireza Zahiroddin
Street address
Imam Hossein Hospital, Shahid Madani St. Tehran
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,Shahid Beheshti 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

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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