Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the Effects of Melatonin and Placebo on Cognitive Side Effects of Electroconvulsive Therapy (ECT) in Patients with Mood Disorders: a randomized clinical trial

Protocol summary

Summary

The aim of present study was to evaluate the effect of Melatonin on prevention of cognitive dysfunction after treatment of mood disorder in patients with electroconvulsive therapy (ECT). In this phase three, single center, randomized double-blind clinical trial, 40 patients with mood disorders admitted to psychiatry ward, who were candidate of ECT therapy, were included the study. Patients with mood disorder who were between 18 and 65 years of age were included and patients with history of substance abuse and previous ECT were excluded from the study. Patients were randomly allocated to two groups using random number table. Intervention group received Melatonin pill (one tablet (3mg) per day,) and control group received placebo pills (one tablet per day) for 4 weeks. Melatonin and placebo pills were identical in appearance and physicians as well as the patients were not aware of the type of pill. Patients were evaluated by mini-mental status examination (MMSE) questionnaire before and after the end of all ECT sessions and also 6 months after intervention. Change in mental status, measured by MMSE questionnaire, was compared between the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015103124793N1**
Registration date: **2016-12-20, 1395/09/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-20, 1395/09/30

Registrant information

Name

Taleb Badri

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Anesthesiology Research Center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effects of Melatonin and Placebo on Cognitive Side Effects of Electroconvulsive Therapy (ECT) in Patients with Mood Disorders: a randomized clinical trial

Public title

Effects of Melatonin on Cognitive Dysfunction After Electroconvulsive Therapy (ECT)

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: affective disorders lead to hospitalization in psychiatric wards; age 18 to 65 years; having informed consent. Exclusion criteria: substance abuse; schizophrenia; previous treatment with electroconvulsive therapy; having psychosis
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
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
patients were randomly allocated to two intervention and control group using random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd, Velenjak, Tehran-Iran
City
Tehran
Postal code
198571151
Approval date
2015-11-19, 1394/08/28
Ethics committee reference number
IR.SBMU.RAM.REC.1394.323

Health conditions studied

1

Description of health condition studied
Mood Disorders
ICD-10 code
F30-F39
ICD-10 code description
Mood [affective] disorders

Primary outcomes

1

Description
Patients' mental status
Timepoint
pretreatment, after finishing ECT sessions, 4 weeks after finishing all sessions
Method of measurement
Mini-mental Status Examination Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Melatonine, 3 mg tablet, orally, once a day, for a period of 4 weeks
Category
Treatment - Drugs

2

Description
Placebo tablet, orally, once a day, for a period of 4 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital, Psychiatric Ward
Full name of responsible person
Taleb Badri
Street address
Psychiatric Ward, Baqiyatallah Hospital, Mollasadra avenue, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Anesthesiology Research Center, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Hedayatollah Elyasi

Street address
Anesthesiology Research Center, Ayatollah Taleghani Hospital, Velenjak, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Anesthesiology Research Center, 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

Contact
Name of organization / entity
Baqiyatallah University of Medical Sciences
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Position
MD, Psychiatrist
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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