

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

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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

Melatonin, 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

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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

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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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Web page address**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