

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The Effect of Melatonin on Cognitive Performance Impairment During Electro Convulsive Therapy in Patients with Bipolar Disorder

Protocol summary

The effect of melatonin on cognitive impairment caused by Electroconvulsive therapy

Study aim

Comparison of the improvement score of cognitive function due to Electroconvulsive therapy in patients with bipolar disorder in two groups receiving melatonin and placebo.

Design

Clinical trial with a control group, with parallel groups, 3 blind strains, randomized, phase 3 on 46 patients. Block randomization method was used for randomization.

Settings and conduct

The current study is a Triple blinded randomized clinical trial. In this study, 46 patients over 18 years of age suffering from bipolar disorder treated with Electroconvulsive therapy were randomly assigned to two drug and placebo groups. Patients in the drug group will receive 3 mg melatonin tablets in the form of 1 oral tablet 2 times a day from 24 hours before the start of Electroconvulsive therapy to 24 hours after the end of Electroconvulsive therapy. Only the ward nurse will be aware of the patient's treatment group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years of age with bipolar disorder, and at the beginning of treatment with Electroconvulsive therapy. Exclusion criteria: schizophrenia, psychiatric illnesses with other mental illnesses, liver or kidney failure, history of seizures, drug or alcohol use, history of melatonin allergy, Pregnancy, breastfeeding.

Intervention groups

In this study, 46 patients over 18 years of age with bipolar disorder treated with Electroconvulsive therapy who meet the inclusion criteria were randomly assigned to two drug and placebo groups. Patients in the drug group will receive 3 mg melatonin tablets manufactured by Simorgh Daru Company in the form of 1 oral tablet 2 times a day from 24 hours before the start of Electroconvulsive therapy to 24 hours after the end of Electroconvulsive therapy.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054879N5**

Registration date: **2023-05-27, 1402/03/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-27, 1402/03/06**

Update count: **0**

Registration date

2023-05-27, 1402/03/06

Registrant information

Name

maryam shahrokhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9026

Email address

mshahrokhi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-26, 1402/03/05

Expected recruitment end date

2023-11-26, 1402/09/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Melatonin on Cognitive Performance Impairment During Electro Convulsive Therapy in Patients with Bipolar Disorder

Public title

Effect of Melatonin on Cognitive Performance Impairment

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients over 18 years of age who are diagnosed with bipolar according to Diagnostic and Statistical Manual of Mental Disorders V (DSM-V) criteria and based on the diagnosis of a psychiatrist, and at the beginning of ECT treatment, refer to Rasht Shafa Hospital.

Exclusion criteria:

Schizophrenia Drug Abusers Psychiatric diseases with other mental illnesses Bradyarrhythmia Liver or kidney failure History of seizures Drug or alcohol use History of asthma or bronchospasm History of allergy to melatonin Pregnancy Breastfeeding Currently uncontrolled hypertension Active peptic ulcer Receiving nitroglycerin History of severe skin disease such as Steven Johnson.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

The case group was named A and the control group was named B. Random blocking is in this way that research units were assigned number 1 to 46 in order. Then a table with 23 rows named block and each block had 2 parts and each part was labeled with A and B was named, considered. In the next step, the numbers will be placed in each house in order. After all the numbers were placed in the blocks, the people who had numbers in house A received the intervention drug, and the people who had numbers in house B, they were considered as the control group. The website <https://www.sealedenvelope.com> is used for randomization. The treatment group of each patient will be determined only after randomization. Allocation Concealment method: Opaque envelopes sealed with a random sequence (snose) are used.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The treatment group of each patient will be determined only after randomization. The participants and the medical doctors responsible for taking care of the health of the patients and the researcher will be blinded and will not know about the treatment group. Only the ward nurse will be aware of the patient's treatment group and will open the relevant envelope. In addition, the research evaluators and statistics experts will be blinded to the treatment group of patients. In order to hide the random allocation, the Numbered Sequentially Envelopes method is used: envelopes sealed, opaque.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Guilan University of Medical Sciences

Street address

Rasht, Namjo St., Shahid Siadati St., in front of 17 Shahrivar Hospital, Research and Technology Deputy

City

Rasht

Province

Guilan

Postal code

4193713111

Approval date

2023-05-03, 1402/02/13

Ethics committee reference number

IR.GUMS.REC.1402.080

Health conditions studied**1****Description of health condition studied**

Bipolar

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes**1****Description**

The primary measurable outcome in this study is the

evaluation of cognitive disorders caused by electroshock therapy in bipolar patients treated with melatonin by the Mini-Mental State Examination questionnaire, which is evaluated before and after 12 sessions of electroshock therapy.

Timepoint

Before and after 12 sessions of electroshock therapy.

Method of measurement

Mini-Mental State Examination questionnaire

Secondary outcomes

1

Description

The examination of changes in systolic and diastolic blood pressure

Timepoint

Before and after each session

Method of measurement

The blood pressure of the patients are checked and measured by the doctor and the researcher every time the patient visits.

2

Description

Check heart rate changes

Timepoint

Before and after each session

Method of measurement

The heart rate of the patients is checked and measured by the doctor and the researcher every time the patient visits.

3

Description

Investigation of possible drug side effects

Timepoint

Before and after each session

Method of measurement

Patients are examined by doctors and researchers at each visit.

Intervention groups

1

Description

Intervention group: 23 Patients in the intervention group will receive 3 mg melatonin tablets manufactured by Simorgh Daru Company in the form of 1 oral tablet 2 times a day from 24 hours before the start of ECT to 24 hours after the end of ECT.

Category

Treatment - Drugs

2

Description

Control group:23 Patients in the control group will

receive placebo tablets manufactured by Simorgh Daru Company in the form of 1 oral tablet 2 times a day from 24 hours before the start of Electroconvulsive Therapy to 24 hours after the end of Electroconvulsive Therapy.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shafa Rasht Hospital

Full name of responsible person

Amirmahdi Rezapour

Street address

Rasht - Mosli Square - 15 Khordad St. - Shafa Medical Education Center

City

Rasht

Province

Guilan

Postal code

41936-55599

Phone

+98 13 3366 2325

Email

shafahospitalrasht@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Gerash University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

Street address

Rasht, Namjo St., Shahid Siadati St., in front of 17 Shahrivar Hospital, Research and Technology Deputy

City

Rasht

Province

Guilan

Postal code

4193713111

Phone

+98 13 3334 5308

Email

Oia.int@gums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Gerash University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Maryam Shahrokhi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
17 Shahrivar Hospital, Shahid Siadati Street, Namjoo
Street, Rasht
City
Rasht
Province
Guilan
Postal code
4144654379
Phone
+98 13 3336 9019
Email
shahrokhi.mail85@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Maryam Shahrokhi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
17 Shahrivar Hospital, Shahid Siadati Street, Namjoo
Street, Rasht
City
Rasht
Province
Guilan
Postal code
4144654379

Phone
+98 13 3336 9019
Email
shahrokhi.mail85@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Amirmahdi Rezapour
Position
Pharmacy student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Rasht-Namjo-in front of Azadi Stadium-No. 25 Nazari
Alley
City
Rasht
Province
Guilan
Postal code
4144673857
Phone
+98 13 3333 3380
Email
amirmahdi.rezapour77@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

According to the approval of the ethics committee of Guilan University of Medical Sciences, in order to respect the privacy of patients, there is no plan to publish the results of patients.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available