Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of N-Acetyl cysteine on Cognitive performance Impairment During Electro Convulsive Therapy in Patients with Bipolar disorder

Protocol summary

Study aim

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

Design

Clinical trial with a control group, with parallel groups, Triple-blind , randomized, phase 3 on 52 patients. Block randomization method was used for randomization.

Settings and conduct

Bipolar patients candidates for electroshock therapy who are hospitalized in Shafa hospital, Rasht will be randomly assigned to intervention and control groups by the random block method. Patients, investigators, and data analyzer will be blinded to the study groups.

Participants/Inclusion and exclusion criteria

Patients older than 18 years of age with bipolar disorder, and at the beginning of treatment with Electroconvulsive therapy. Exclusion criteria: schizophrenia, liver or kidney failure, history of seizures, drug or alcohol use, history of n-acetyl cysteine allergy, Pregnancy, breastfeeding.

Intervention groups

Intervention group: 26 Patients in the intervention group will receive one 600 mg oral n-acetyl cycteine effervescent tablet manufactured by Osve Company, every 12 hours, from 24 hours before the start of Electroconvulsive therapy (ECT) to 24 hours after the end of ECT. Usually, patients receive 6 sessions of electroconvulsive therapy, therefore, the duration of drug treatment will be two weeks. Control group: 26 Patients in the control group will receive one placebo manufactured by Osve Company, every 12 hours, from 24 hours before the start of Electroconvulsive therapy (ECT) to 24 hours after the end of ECT. Usually, patients receive 6 sessions of electroconvulsive therapy, therefore, the duration of drug treatment will be two weeks.

Main outcome variables

Cognitive impairment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054879N7**
Registration date: **2023-07-09, 1402/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-09, 1402/04/18**
Update count: **0**

Registration date

2023-07-09, 1402/04/18

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 N-Acetyl cysteine on Cognitive performance Impairment During Electro Convulsive Therapy in Patients with Bipolar disorder

Public title

The Effect of N-Acetyl cysteine on Cognitive performance Impairment

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with bipolar disorder older than 18 years Treatment with electroconvulsive therapy

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 n-acetyl cycteine 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
- Investigator
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed by blocks of size 4, using sealedenvelope.com website. For allocation concealment, opaque envelopes sealed with a random sequence (snose) will be used.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this triple-blinded study, the patient, the investigator, and the data analyzer were blinded to the studied groups. Sealed envelopes for randomization, drug and placebo in similar envelopes are provided to the nurse of the department and when the patient enters, the medicine or placebo is given to the patient based on the code written in the envelope.The patient and the researcher do not know about the treatment group, and only the ward nurse and the patient's caregiver know about the grouping.

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

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

City

Rasht

Province

Guilan

Postal code

4193713111

Approval date

2023-05-17, 1402/02/27

Ethics committee reference number

IR.GUMS.REC.1402.100

Health conditions studied

1

Description of health condition studied

Bipolar

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

Cognitive impairment

Timepoint

Before intervention and two weeks after beginning of the intervention

Method of measurement

Mini-Mental State Examination questionnaire

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

Before the intervention and two weeks after beginning of the intervention

Method of measurement

Digital blood pressure measurement device

2

Description
Diastolic blood pressure
Timepoint
Before the intervention and two weeks after beginning of the intervention
Method of measurement
Digital blood pressure measurement device

Intervention groups

1

Description
Intervention group: 26 Patients in the intervention group will receive one 600 mg oral n-acetyl cycteine effervescent tablet manufactured by Osve Company, every 12 hours, from 24 hours before the start of Electroconvulsive therapy (ECT) to 24 hours after the end of ECT. Usually, patients receive 6 sessions of electroconvulsive therapy, therefore, the duration of drug treatment will be two weeks.
Category
Treatment - Drugs

2

Description
Control group: 26 Patients in the control group will receive one placebo manufactured by Osve Company, every 12 hours, from 24 hours before the start of Electroconvulsive therapy (ECT) to 24 hours after the end of ECT. Usually, patients receive 6 sessions of electroconvulsive therapy, therefore, the duration of drug treatment will be two weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Rasht Hospital
Full name of responsible person
Daniyal Siahtiri
Street address
Shafa Medical Education Center ,15 Khordad St , Mosli Square , Rasht town.
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
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
Street address
Research and Technology Deputy , 17 Shahrivar Hospital, Shahid Siadati Street, Namjoo Street, Rasht town.
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
Rasht 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
Daniyal Siahtiri
Position
Pharmacy student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
No.37, Shirmohammadi Ave , Emam blvd to Farhang square , Rasht town.
City
Rasht
Province
Guilan
Postal code
4144673857
Phone
+98 13 3333 3380
Email
Daniyal97siahtiri@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