Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The effectiveness of omega-3 adjuvant therapy to Electroconvulsive therapy (ECT) in bipolar patients in a manic episode

Protocol summary

Study aim
The effectiveness of omega-3 adjuvant therapy toElectroconvulsive therapy (ECT) in bipolar patients in a manic episode

Design
A randomized clinical trial with the parallel control group, double-blind; Phase 2-3, on 50 patients, the patients will be randomly assigned to intervention and control groups using block randomization.

Settings and conduct
This study is performed on bipolar patients in the acute phase of mania which, according to the doctor's opinion, needed to receive ECTin Farshchian Hospital in Hamadan. The patient and the examining physician will not be aware of the patient's type of drug treatment so the study will be double-blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Bipolar patients in the acute phase of mania who, according to the physician, needed ECT; Age greater than or equal to 18; Young Mania Rating Scale greater than or equal to 20; Having at least fifth-grade education Exclusion criteria: Psychiatric disorders except for Bipolar Disorder;Pregnancy or breastfeeding; Having a history of substance abuse in the last 2 weeks or addiction in the previous 2 months; Having a systemic disease

Intervention groups
Intervention group: 25 patients with bipolar disorder in the mania phase are treated with electroshock therapy with 100 mg omega-3 capsules(manufactured by Zahravi company) for 4 weeks. Control group: 25 patients with bipolar disorder in the mania phase are treated with electroshock therapy with a placebo (manufactured by Zahravi company) for 4 weeks.

Main outcome variables
Cognitive function, sleep quality, Young Mania questionnaire score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160523028008N26**
Registration date: **2022-09-13, 1401/06/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-13, 1401/06/22**
Update count: **0**

Registration date
2022-09-13, 1401/06/22

Registrant information

Name
Mohammad Faryadras

Name of organization / entity
Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2022-11-21, 1401/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of omega-3 adjuvant therapy to Electroconvulsive therapy (ECT) in bipolar patients in a manic episode

Public title
The effect of adding omega-3 in bipolar patients during manic period requiring ECT.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Bipolar patients in the acute phase of mania who, according to the physician, needed ECT Age greater than or equal to 18 Young Mania Rating Scale greater than or equal to 20 Having at least fifth grade education

Exclusion criteria:
Psychiatric disorders except Bipolar Disorder Pregnancy or breastfeeding Having a history of substance abuse in the last 2 weeks or addiction in the last 2 months Having a systemic disease

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The form of the drug and the placebo are completely the same, so the patient and the examining physician will not be aware of the patient's type of drug treatment, so the study will be performed in a double-blind manner.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2022-06-25, 1401/04/04

Ethics committee reference number
IR.UMSHA.REC.1401.325

Health conditions studied

1

Description of health condition studied
Bipolar Disorder, current episode manic severe with psychotic features

ICD-10 code
F31.2

ICD-10 code description
Bipolar Disorder, current episode manic severe with psychotic features

Primary outcomes

1

Description
mania symptoms

Timepoint
Before the intervention, after the fourth and eighth sessions of ECT.

Method of measurement
Young Mania Rating Scale (YMRS)

2

Description
Cognitive function

Timepoint
Before and after the intervention

Method of measurement
Cognitive function Test by using Montreal Cognitive Assessment

3

Description
sleep quality

Timepoint
Before and after the intervention
Method of measurement
Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 25 patients with bipolar disorder in the mania phase are treated with electroshock therapy with 100 mg omega-3 capsules (manufactured by Zahravi company) as a single daily oral dose for 4 weeks. The number of electroshock therapy sessions is 8 sessions, which are done on a day in the middle under standard conditions.
Category
Treatment - Drugs

2

Description
Control group: 25 patients with bipolar disorder in the mania phase are treated with electroshock therapy with a placebo (manufactured by Zahravi company) for 4 weeks. The number of electroshock therapy sessions is 8 sessions, which are done on a day in the middle under standard conditions.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Ali Ghaleiha
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh street
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Khadijeh Arabloo
Position
Resident Psychiatric
Latest degree
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Person responsible for updating data

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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
There is not a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available