

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of thiamine on cognitive symptom in the patients with mood disorder in the depression phase under electroconvulsive therapy (clinical trial- double blind)

Protocol summary

Study aim

Effect of thiamine on cognitive symptom in the patients with mood disorder in the depression phase under electroconvulsive therapy.

Design

A randomized clinical trial with control group, with parallel groups, phase 3. with blindness that, 62 patients randomly divided into two groups of 31 subjects with block sizes of 4.

Settings and conduct

The study population included patients referred to the psychiatric ward of Yahya Nejad Hospital who will undergo electroshock therapy (ECT). Patients' cognitive ability will be assessed 24 hours before and 24 hours after the end of ECT sessions and also two months after the end of ECT using the Eden Brook cognitive examination test. The hour after the end of the electroshock therapy sessions and also two months later will be used. This test is performed by a trained tester in 15 to 20 minutes.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 20-50 years with depressive phase of mood disorders
Exclusion Criteria: Patients with a history of alcohol and other substance use in the month before enrollment, Epilepsy, Mental retardation, Cognitive disorders such as delirium and dementia, History of thiamine use in the month before enrollment, Anemia and Malnutrition

Intervention groups

Intervention group: Thiamine (pharmaceutical drug Sanamod) will be started 24 hours before electroconvulsive therapy at a dose of 100 mg daily and this daily dose will continue for up to 8 weeks. Control group: Placebo will be started 24 hours before electroconvulsive therapy at a dose of 100 mg daily and this daily dose will continue for up to 8 weeks

Main outcome variables

Cognitive ability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190525043700N3**

Registration date: **2021-03-12, 1399/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-12, 1399/12/22**

Update count: **0**

Registration date

2021-03-12, 1399/12/22

Registrant information

Name

Romina Hamzehpour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-10, 1399/12/20

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of thiamine on cognitive symptom in the patients with mood disorder in the depression phase under electroconvulsive therapy (clinical trial- double blind)

Public title

The effectiveness of thiamine on cognitive symptoms after electroconvulsive therapy in patients with mood disorders

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 20-50 years with depressive phase of mood disorders

Exclusion criteria:

Patients with a history of alcohol and other substance use in the month before enrollment Epilepsy Mental retardation Cognitive disorders such as delirium and dementia History of thiamine use in the month before enrollment Anemia Malnutrition

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients randomly divided into two groups of 31 subjects with four blocks and an allocation ratio of 1: 1. The free website [WWW.randomization .com](http://WWW.randomization.com) was used to generate the allocation sequence. The obtained sequence was written on separate sheets and placed in sealed envelopes and given to the main researcher for study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Thiamine tablets are powdered by a mortar and the placebo is filled with flour and poured into separate capsules. The shape, taste, smell and packaging of the drugs are quite similar. A code is assigned to each container of medicine. When the drug is assigned to the patient, the drug code will be entered on the file. At the end of the study, the codes will be opened and the results will be analyzed.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Babol University Of Medical Sciences

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Daneshgah Square, Ganjafrooz Avenue

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Approval date

2021-02-20, 1399/12/02

Ethics committee reference number

IR.MUBABOL.REC.1399.488

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

Cognitive Symptom

ICD-10 code

R41

ICD-10 code description

Other symptoms and signs involving cognitive functions and awareness

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

Cognitive ability

Timepoint

It will be measured 24 hours before and 24 hours after the end of electroconvulsive therapy sessions and also two months after the end of electroconvulsive therapy.

Method of measurement

Addenbrooke's Cognitive Examination

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Thiamine (pharmaceutical drug

Sanamod) will be started 24 hours before electroconvulsive therapy at a dose of 100 mg daily and this daily dose will continue for up to 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo will be started 24 hours before electroconvulsive therapy at a dose of 100 mg daily and this daily dose will continue for up to 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahya Nejad Hospital

Full name of responsible person

Roumina Hamzehpour

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Shahid Mostafa Khomeini St., Modarres St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Romina Hamzehpour

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

Contact

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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 still no plan for its publish.

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

Undecided - It is not yet known if there will be 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