

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Thiamine on Cognitive Performance of Patients Under Electro-Convulsive Therapy: A Randomized Double Blind Clinical Trial.

Protocol summary

Study aim

Determine Effectiveness of Thiamine on Cognitive Performance of Patients Under Electro-Convulsive Therapy(ECT) .

Design

: Randomized Double Blind controlled Clinical Trial

Settings and conduct

The study is performed on hospitalized patients in Sanandaj Qods Hospital who receive ECT.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalization in Qods Hospital ; Age between 18 and 60 years ; Signing informed consent form by patient or his legal guardian ; Number of sessions of ECT between 6 to 12 sessions and Exclusion criteria : Having alcohol dependence in the past 3 months except nicotine and caffeine ; Mental retardation ; Causes of delirium and dementia and cognitive impairment ; History of thiamine use in the previous 3 months and History of allergy to thiamine.

Intervention groups

The intervention group received a capsule containing 100 mg of thiamine twice daily and the control group received a placebo capsule twice daily during the ECT.

Main outcome variables

Wechsler test and MMSE scores

General information

Reason for update

Acronym

Sanandaj Thiamine study

IRCT registration information

IRCT registration number: **IRCT20191218045795N4**

Registration date: **2020-05-03, 1399/02/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-03, 1399/02/14**

Update count: **0**

Registration date

2020-05-03, 1399/02/14

Registrant information

Name

Narges Shams alizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 8821

Email address

n.shamsalizadeh@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-29, 1398/12/10

Expected recruitment end date

2021-09-01, 1400/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Thiamine on Cognitive Performance of Patients Under Electro-Convulsive Therapy: A Randomized Double Blind Clinical Trial.

Public title

Efficacy of Thiamine in Amnesia due to Electro Convulsive Therapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate for ECT ; Age between 18-60 years

old. The Patient or his or her legal guardian must sign the informed consent form. The number of Electro Convulsive Therapy sessions ; must be between 2-12 sessions.

Exclusion criteria:

Alcohol and substance dependence except Caffeine and Nicotine in past 3 months. Proven Intelligent Disability or diagnosed with assistant. History of Delirium, Dementia and Cognitive Disorders. History of Thiamine consumption from 3 months before the visit. History of Thiamine sensitivity.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The random assignment of patients is done by the resident implementing the plan using pre-determined envelopes. The random allocation list is provided to the pharmacist by the block method provided by the methodological consultant. Required drugs are embedded in envelopes and numbered. Can be arranged in order to be given to patients. The drugs will be administered in two groups and will be similar in appearance. Wounded Patients who are evaluating outcomes, being a patient psychiatrist, will not be aware of grouping. Quadratic random blocking is also used for random allocation as follows: The 4-way random blocking method is as follows and its blocks include: AABB 1 For Group A patients And for Group B patients BABA BBAA ABAB AABB ABBA BAAB BABA BABA ABBA BBAA AABB BABA ABAB BAAB BBAA 2 ABAB 3 BABA 4 ABBA 5 BAAB 6

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients (participants) and outcome assessors, project researchers, patient therapist psychiatrists, and nurse staff who give medication were kept blind in the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kurdistan University of Medical Sciences

Street address

Pasdaran blv, Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

6617978743

Approval date

2020-03-15, 1398/12/25

Ethics committee reference number

IR.MUK.REC.1398.308

Health conditions studied

1

Description of health condition studied

Schizophrenia, Schizoaffective, Mood disorders and Obsessive-compulsive disorders

ICD-10 code

F20,, F25,,

ICD-10 code description

Schizophrenia , Schizoaffective disorder. Bipolar affective disorder. Obsessive_compulsive disorder, Mood disorder (manic episode). Mood disorder (Depressive episode)

Primary outcomes

1

Description

Memory

Timepoint

1day before begining and after ending the Electro Convulsive Therapy

Method of measurement

wechsler

2

Description

Memory

Timepoint

1day before begining and after ending the Electro Convulsive Therapy

Method of measurement

mini mental status examination

Secondary outcomes

1

Description

tremor

Timepoint

During the intervention

Method of measurement

Patient Self Report

2

Description

confusion

Timepoint

During the intervention

Method of measurement

Patient Self Report

3

Description

Headache

Timepoint

During the intervention

Method of measurement

Patient Self Report

4

Description

nausea

Timepoint

During the intervention

Method of measurement

Patient Self Report

Intervention groups

1

Description

Intervention group: Thiamine 100 mg capsul Twice a day(morning & night) in the intervention group

Category

Prevention

2

Description

Intervention group:

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods hospital

Full name of responsible person

Narges Shamsalizadeh

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Postal code

6617794795

Email

n.shamsalizadeh@muk.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Ghaderi

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e.ghaderi@muk.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Narges Shamsalizadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

participant individual data

When the data will become available and for how long

6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

After completing the study, it will be determined

From where data/document is obtainable

email: nshamsalizadeh@yahoo.com

What processes are involved for a request to access data/document

3 montj

Comments