Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim
Determine Effectiveness of Thiamine on Cognitive Performance of Paitients 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 Paitients Under Electro-Convulsive Therapy: A Randomized Double Blind Clinical Trial.

Public title
Efficacy of Thiamine in Amnisia due to Electro Convulsive Therapy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients candicate 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 dosorders and Obsessive-compulsive disorders

ICD-10 code

F20,,F25,,

ICD-10 code description

Schizophrenia ,Schizoaffective disorder.Bipolar affective disoeder.Obssessive_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
cofusion
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
Street address
Pasdaran
City
Sanandaj
Province
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Postal code
6617794795
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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
Street address
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Postal code
6617794795
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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

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Person responsible for updating data

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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