

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2026

The effect of levothyroxine on ECT Induced Memory Impairment in bipolar patients

Protocol summary

Summary

The purpose of the study is to assess the effectiveness of using levothyroxine in reducing memory loss of bipolar patients as a result of electric convulsive therapy(ECT). Inclusion criteria:Diagnosis of bipolar disorder using structured clinical interview for Dsm disorders (SCID);indication for a psychiatrist-recommended ECT ;An age range of 18-64;consent letter obtained from patient's parents. Exclusion criteria:Any contraindication of levothyroxine;Comorbidity of substance or alcohol dependency;Any organic brain disorders or mental retardation (based on patient's history, physical examination and records) or any cognitive disorders (MMSE<23) at the advent of the study;ECT less than 6 sessions;ECT-induced delirium;taking none of the standard mood-stabilizing drugs (sodium valproate ,lithium carbonate nor carbamazepin); taking more than one standard mood- stabilizing drug (sodium valproate ,lithium carbonate or carbamazepin);receiving more than one convulsion in ECT in half of the sessions;siezure duration lower than15 seconds in more than half of the sessions;siezure duration higher than 3 minutes even in one session;The study population included 48, type-I bipolar patients taking prescribed ECT from September 2016 to May 2017.During the treatment,the intervention group received 0 / 1 mg of levothyroxine with the control group taking placebo. The average amount of memory loss in both groups was measured and compared using the Wechsler memory test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071012018N3**

Registration date: **2016-09-16, 1395/06/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-16, 1395/06/26

Registrant information

Name

Hossein Javdani

Name of organization / entity

Tabriz university of medical sciences

Country

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Phone

+98 41 1441 2002

Email address

javdanih@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

reasercher

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of levothyroxine on ECT Induced Memory Impairment in bipolar patients

Public title

The effect of levothyroxine on ECT Induced Memory Impairment in bipolar patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Diagnosis of bipolar disorder based on SCID questionnaire that its persian validity and reliability is confirmed:Presence of ECT indication is under recommendation of psychiatrist:Age between 18-64:consent letter of patient's parents.Exclusion criteria:Any contraindication of levothyroxine:Comorbidity of substance or alcohol dependence:Any organic brain disorder or mental retardation (based on history, physical exam and patient's records) or any cognitive impairment(MMSE<23) at begining of study:ECT less than 6 session:ECT induced delirium:not using at least one of standard mood stabilizers (sodium valproate ,lithium carbonate or carbamazepin):use more than one of standard mood stabilizers (sodium valproate ,lithium carbonate or carbamazepin):use more than one convulsion in ECT in at least half of sessions:siezure duration below 15 second in more than half of sessions:siezure duration higher thant 3 minutes in even one session:

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University Of Medical Science

Street address

Shahid Bahonar Blv Qazvin Iran

City

Qazvin

Postal code

Approval date

2015-11-08, 1394/08/17

Ethics committee reference number

IR.QUMS.REC.1394.202

Health conditions studied

1

Description of health condition studied

BIPOLAR affective disorder

ICD-10 code

F31

ICD-10 code description

Bipolar affective disorder

Primary outcomes

1

Description

memory impairment

Timepoint

Baseline and Then two weeks after completion of therapy

ذغذ

Method of measurement

wecsler memory tese

Secondary outcomes

1

Description

cognitin state

Timepoint

Baseline and Then two weeks after completion of therapy

ذغذ

Method of measurement

mmse

Intervention groups

1

Description

tablet levothyroxine 0.1 mg daily fasting during ECT treatment

Category

Treatment - Drugs

2

Description

Tablet Placebo(similar Levothyroxine) daily Fasting during ECT treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital
Full name of responsible person
Seyed Majid Hoseiny Hoshyar
Street address
22 Bahman Hospital Rah_ahan ave Qazvin
City
Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Science
Full name of responsible person
Taghi Naserpoor
Street address
Shahid Bamonar blv Qazvin
City
Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Science
Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty