

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the Effectiveness of Ginkgo Biloba regimen on cognitive function in patients undergoing electroconvulsive therapy: Double blind clinical trial

Protocol summary

Study aim

Evaluation of the Effectiveness of Ginkgo Biloba regimen on cognitive function in patients undergoing electroconvulsive therapy: Double blind clinical trial

Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, phase 3 on 80 patients with randomized Random block permutation method.

Settings and conduct

The present study was performed as a double-blind phase 3 clinical trial in the psychiatric ward of Ahvaz Golestan Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients admitted to the psychiatric ward of Ahvaz Golestan Hospital aged 18 to 60 years whose illness has been confirmed by a psychiatrist

Exclusion criteria: History of epilepsy, History of coagulation disorders, History of alcohol and drug abuse, History of drug allergy, Patients who have received electroconvulsive therapy in the last 6 months before study

Intervention groups

Case group: Ginkgo biloba administrated 48 hours before shock therapy. The case group is given 6-12 bilateral or unilateral ECT sessions (3 times a week) and one Ginkgo biloba tablet (200 mg tablet) daily after meals until the end of ECT sessions. Control Group: Placebo administrated 48 hours before shock therapy. The case group is given 6-12 bilateral or unilateral ECT sessions (3 times a week) and one Placebo capsule daily after meals until the end of ECT sessions.

Main outcome variables

Mini-Mental State Examination scale , Wechsler Memory Scale III scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200516047470N1**

Registration date: **2020-08-21, 1399/05/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

Name

Elham Zeynali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3038

Email address

zeynali_e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effectiveness of Ginkgo Biloba regimen on cognitive function in patients undergoing electroconvulsive therapy: Double blind clinical trial

Public title

Evaluation of the Effectiveness of Ginkgo Biloba regimen on cognitive function in patients undergoing electroconvulsive therapy: Double blind clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients admitted to the psychiatric ward of Ahvaz Golestan Hospital aged 18 to 60 years whose illness has been confirmed by a psychiatrist

Exclusion criteria:

History of epilepsy History of coagulation disorders
History of alcohol and drug abuse History of drug allergy
Patients who have received electroconvulsive therapy in the last 6 months before study

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Because we would like two study groups have the same sample size, we will use block randomization by Statistical Analysis System (SAS). Blocking is used to create the number of samples in the number of samples assigned to each of the studied groups. In this research, four random blocks are used. In a way that , after sampling, according to the order of eligible participants entrance to study, the designated group of the participant will become apparent, and just allocated person knows it and the researcher and sampler will never understand which sample will enter to the intervening group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the researcher, clinical evaluator, analyst, and patient are unaware of which drug or placebo is in either group. Medications and placebos will be similar in shape, color, and taste.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapour University of Medical Sciences

Street address

Ahvaz Jundishapour University of Medical Sciences, Golestan blv, Ahvaz, Iran

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Approval date

2019-12-28, 1398/10/07

Ethics committee reference number

IR.AJUMS.REC.1398.700

Health conditions studied

1

Description of health condition studied

Psychosis

ICD-10 code

F15

ICD-10 code description

Other stimulant related disorders

Primary outcomes

1

Description

Mini-Mental State Examination

Timepoint

Before, during and after the intervention

Method of measurement

Mini-Mental State Examination Scale

2

Description

Memory

Timepoint

Before, during and after the intervention

Method of measurement

Wechsler Memory Scale III

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ginkgo biloba administrated 48 hours before shock therapy. The case group given 6-12 bilateral or unilateral ECT sessions (3 times a week) and one Ginkgo biloba tablet (200 mg tablet) daily after meals until the end of ECT sessions.

Category

Treatment - Drugs

2

Description

Control group: Placebo administrated 48 hours before shock therapy. The control group given 6-12 bilateral or unilateral ECT sessions (3 times a week) and one Placebo tablet daily after meals until the end of ECT sessions.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Masumeh Nazarinasab

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Jundishapour University of Medical Sciences, Golestan blv, Ahvaz, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Elham Zeynali

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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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

Not applicable

Title and more details about the data/document

It depends on the university

When the data will become available and for how long

It depends on the university

To whom data/document is available

It depends on the university

Under which criteria data/document could be used

It depends on the university

From where data/document is obtainable

It depends on the university

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

It depends on the university

Comments