Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Khouzestan
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
Street address
Jundishapour University of Medical Sciences, Golestan blv, Ahvaz, Iran
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Nazarinasab-m@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Ahvaz Jundishapour University of Medical Sciences, Golestan blv, Ahvaz, Iran
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Email
src@ajums.ac.ir
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
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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