Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of galantamine on cognitive performance of patients under electro convulsive therapy

Protocol summary

Study aim
Efficacy of galantamin on cognitive performance of patients under electro convulsive therapy

Design
Clinical trial, with control group, double blind, randomized, phase 3, 90 patients

Settings and conduct
90 patients from psychiatric wards, men and women, in Sanandaj Qods hospital were candidate for ECT treatment and had the criteria to enter study and collected randomly allocated in either placebo or intervention groups. In this study participant, care provider (nurse), investigator were blind. In both groups in addition to electroconvulsive therapy, 4mg Galantamine capsules of one form and placebo in the other group were prescribed twice a day. Patients were evaluated with wechsler test and Mini mental status examination on the day before the intervention and after the third session and after the end of the electroconvulsive therapy.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of patient between 18-60 years.the patients or their legal guardian must sign an informed consent form. Number of sessions of ECT between 4-8, Exclusion criteria: Alcohol&drug abuse or dependance, renal failure, ischemic heart disease, stroke in last 6 months, Delirium and Dementia, pregnancy and lactation, history of using galantamin in last 3 months, Galantamine sensitivity, mental retardation.

Intervention groups
One group received 8mg galantamin daily. Other group received placebo

Main outcome variables
Memory

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200207046404N1**
Registration date: **2020-04-23, 1399/02/04**
Registration timing: **retrospective**

Last update: **2020-04-23, 1399/02/04**
Update count: **0**

Registration date
2020-04-23, 1399/02/04

Registrant information

Name
Aziz alah Ghanbari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3362 6968

Email address
ravanmehr20@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-01, 1397/07/09

Expected recruitment end date
2019-05-01, 1398/02/11

Actual recruitment start date
2018-10-01, 1397/07/09

Actual recruitment end date
2019-05-01, 1398/02/11

Trial completion date
2019-09-02, 1398/06/11

Scientific title
Efficacy of galantamine on cognitive performance of patients under electro convulsive therapy

Public title

Efficacy of galantamine on cognitive performance

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged between 18-60 years Patients or their legal guardian must sign an informed consent form Number of sessions of ECT between 4-8

Exclusion criteria:

Alcohol & drug abuse or dependence Renal failure Ischemic heart disease Stroke in last 6 months Delirium &Dementia Pregnancy & Lactation History of using Galantamine in past 3 months Galantamine sensitivity Mental retardation

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **75**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients into two intervention or control groups,patients are randomly divided into two groups A and B with a table of random numbers (random numbers table is a collection of numbers that are generated without a specific pattern or order and completely randomized then samples are randomly selected by randomizer software).The numbers are given to the pharmacist, based on which he determines the medicinal packages of galantamine and placebo and no one but him knows which drug and which placebo it is, and the number of each package is recorded in the patient's file.

Blinding (investigator's opinion)

Double blinded

Blinding description

Packages containing medications were prepared by pharmacist and nobody knew their content except the pharmacist. Patients names were randomly assigned into blocks A and B based on random number table insert on the drug envelops and were given medication packages until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdestan University of Medical Sciences

Street address

Kurdestan Medical Sciences Univercity,Pasdaran Ave, Sanandaj Town

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2018-07-03, 1397/04/12

Ethics committee reference number

IR.MUK.REC.1397.096

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

2

Description of health condition studied

Schizoaffective

ICD-10 code

F25

ICD-10 code description

Schizoaffective disorders

3

Description of health condition studied

Mood disorders

ICD-10 code

F06.34

ICD-10 code description

Mood disorder due to known physiological condition with mixed features

4

Description of health condition studied

Obsessive- compulsive disorders

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description
Memory
Timepoint
1day before begining and after session 3 and after the electroconvulsive therapy
Method of measurement
Wechsler, mini mental statuse examination

Secondary outcomes

1

Description
Nausea
Timepoint
During intervention(once a day for 15 days)
Method of measurement
Patient self report

2

Description
Confusion
Timepoint
During intervention(once a day for 15 days)
Method of measurement
Patient self report

3

Description
Dizziness
Timepoint
During intervention(once a day for 15 days)
Method of measurement
Patient self report

Intervention groups

1

Description
Galantamin 4mg capsules BID in the intervention group until the end of ECT treatment.(for 15 days)
Category
Prevention

2

Description
Control group: received placebo capsules BID until the end of ECT treatment.(for 15 days)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Qods Hospital
Full name of responsible person
Azizalah Ghanbari
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Pasdaran Ave
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Http://muk.ac.ir/muk/Hospital/Qods.aspx

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
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Email
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Web page address
Http://muk.ac.ir/muk/Hospital/Qods.aspx
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
Hojat Esfandiyary
Position
Psychologist
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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Person responsible for updating data

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Web page address
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable