

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+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 envelopes 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 Kurdistan University of Medical Sciences

##### Street address

Kurdistan Medical Sciences University, 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

## Primary outcomes

### 1

**Description**

Memory

**Timepoint**

1day before begining and after session 3 and after the electroconvulsive therapy

**Method of measurement**

Wechsler, mini mental statue 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

**Street address**

Pasdaran Ave

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617713446

**Phone**

+98 87 3362 6968

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+98 87 3366 1340

**Email**

Ravanmehr20@gmail.com

**Web page address**

[Http://muk.ac.ir/muk/Hospital/Qods.aspx](http://muk.ac.ir/muk/Hospital/Qods.aspx)

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Azizalah Ghanbari

**Street address**

Pasdaran Ave

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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**

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 Esfandiyari

**Position**

Psychologist

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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**Web page address**

[Http://.Muk.ac.ir/Muk/Hospital/Qods.aspx](http://.Muk.ac.ir/Muk/Hospital/Qods.aspx)

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Azizalah Ghanbari

**Position**

Psychiatrist assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Pasdarane ave

**City**

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**Person responsible for updating data****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Azizalah Ghanbari

**Position**

Psychiatrist Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street 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