Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Efficacy of Donepezil in cognitive impairments of patients under Electro Convulsive Therapy (Randomized Double blind Clinical Trial)

Protocol summary

Summary

The aim of this study assess the efficacy and safety of Donepezil in the prevention of cognitive impairments due to Electro Convulsive Therapy. Method and Material: 70 adult patients that randomly divided into two groups (35 intervention, 35 placebo) with: Inclusion criteria :Patients referring to Sanandaj Qods Hospital ; Age between 18-60 years old; 2-8 sessions Electro Convulsive Therapy; The Patient who fill out the testimonial form; and Exclusion criteria: Alcohol and substance dependence except Caffeine and Nicotine in past 3 months; History of Epilepsy; Proven Intelligent Disability or diagnosed with assistant; History of Delirium, Dementia and Cognitive Disorders ;Pregnancy and breast-feeding; History of using Doneprzil in past 3 months; History of using Paroxetine and Ketoconazol; Donepezil sensitivity; History of Cardiovascular disease; History of Brain Stroke in past 6 months; Head trauma and surgery or traumatic Brain injury in past year Various mental disorders during the Electro Convulsive Therapy period who show cognitive impairments randomly receive Donepezil(5mg/day)or placebo treatment (Randomized Double blind Clinical Trial) .wechsler adult intelligence scale(backward memory span, digit span...) and mini mental status examination are used to assess the cognition function 24 hours before and after the Electro Convulsive Therapy .

General information

Acronym

Sanandaj Donepezil study

IRCT registration information

IRCT registration number: **IRCT2017022532766N1**
Registration date: **2017-04-03, 1396/01/14**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-04-03, 1396/01/14

Registrant information

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2017-04-06, 1396/01/17

Expected recruitment end date

2017-05-05, 1396/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Donepezil in cognitive impairments of patients under Electro Convulsive Therapy (Randomized Double blind Clinical Trial)

Public title

Efficacy of Donepezil in Amnisia due to Electro Convulsive Therapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria :Patients referring to Sanandaj Qods Hospital ; Age between 18-60 years old; 2-8 sessions Electro Convulsive Therapy; The Patient who fill out the testimonial form; and Exclusion criteria: Alcohol and substance dependence except Caffeine and Nicotine in past 3 months; History of Epilepsy; Proven Intelligent Disability or diagnosed with assistant; History of Delirium, Dementia and Cognitive Disorders ;Pregnancy and breast-feeding; History of using Doneprzil in past 3 months; History of using Paroxetine and Ketoconazol; Donepezil sensitivity; History of Cardiovascular disease; History of Brain Stroke in past 6 months; Head trauma and surgery or traumatic Brain injury in past year

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of Medical Sciences

Street address

Pasdaran Ave.

City

Sanandaj

Postal code

6617713446

Approval date

2017-02-13, 1395/11/25

Ethics committee reference number

IR.MUK.REC.1395.339

Health conditions studied

1

Description of health condition studied

Schizophrenia,Schizoaffective,Mood dosorders and Obsessive-compulsive disorders

ICD-10 code

F20,,F25,,

ICD-10 code description

Schizophrenia ,Schizoaffective disorder.Bipolar affective disoeder.Obssessive_compulsive disorder,Mood disorder(manic episode).Mood disorder(Depressive episode)

Primary outcomes

1

Description

Memory

Timepoint

1day before begining and after the Electro Convulsive Therapy

Method of measurement

wechsler

2

Description

Memory

Timepoint

1day before begining and after ending the Electro Convulsive Therapy

Method of measurement

mini mental status examination

Secondary outcomes

1

Description

tremor

Timepoint

During interventiin

Method of measurement

Patient Self Report

2

Description

cofusion

Timepoint

During interventiin

Method of measurement

Patient Self Report

3

Description

Headache

Timepoint

During interventiin

Method of measurement

Patient Self Report

4

Description
nausea
Timepoint
During interventiin
Method of measurement
Patient Self Report

Intervention groups

1

Description
Donepezil 5 mg capsules every night in the intervention group
Category
Prevention

2

Description
control group received placebo capsules per night
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Qods Hospital
Full name of responsible person
Akbar Qanbarzadeh
Street address
Pasdaran Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Akbar Qanbarzadeh
Street address
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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
Kurdistan University of Medical Sciences
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

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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