

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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

###### Name

Akbar Qanbarzadeh Chelan sofa

###### Name of organization / entity

Kurdistan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 87 3366 4653

###### Email address

akbar.qanbarzadeh@muk.ac.ir

##### 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 Amnesia 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,Schizoffective,Mood disorders and Obsessive-compulsive disorders

#### **ICD-10 code**

F20,,F25,,

#### **ICD-10 code description**

Schizophrenia ,Schizoffective disorder.Bipolar affective disorder.Obsessive\_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.

**City**

Sanandaj

### Sponsors / Funding sources

#### 1

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

Kurdistan University of Medical Sciences

**Full name of responsible person**

Akbar Qanbarzadeh

**Street address**

Pasdaran Ave.

**City**

Sanandaj

**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

**Contact****Name of organization / entity**

Qods Hospital

**Full name of responsible person**

Hojat Sfandyari

**Position**

Psychologist

**Other areas of specialty/work****Street address**

Pasdaran Ave.

**City**

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**Postal code**

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**Phone**

+98 87 3366 4653

**Fax****Email**

esfandyari89@gmail.com

**Web page address**

<http://muk.ac.ir/Muk/Hospitals/Qods.aspx>

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Qods Hospital

**Full name of responsible person**

Akbar Qanbarzadeh

**Position**

Psychiatrist assistant

**Other areas of specialty/work****Street address**

Pasdaran Ave.

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Qods Hospital

**Full name of responsible person**

Akbar Qanbarzadeh

**Position**

Psychiatrist assistant

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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*