

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluation of Donepezil effectiveness on prevention of cognitive impairment caused by electroconvulsivetherapy (ECT) in mood disorder patients

#### Protocol summary

Decrease cognitive impairment in Donepezil group

##### Study aim

Evaluation the effectiveness of Donepezil on prevention of cognitive impairment caused by electroconvulsive therapy in mood disorder patients

##### Design

Pragmatic, community based, parallel group, double blind, randomised controlled tria

##### Settings and conduct

94 patients from psychiatric wards of men and women in Hajar Hospital were collected and randomly allocated in either placebo or intervention group. In this study Participant, Care provider(nurses), Investigator, data collectors and Outcome assessor are blinded. Intervention group received Donepezil with dose of 5 mg per day at the start of study to 1 month after the end of electroconvulsivetherapy and placebo group received placebo with the same color and shape like Donepezil. Patient were assessed using MMSE and ACER scales before ECT, before session 4 and a month after end of ECT

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 15-65 years old, Diagnosis of Major depressive disorder, Diagnosis of bipolar disorder, Prescribing at least four session of electroconvulsivetherapy, inform consent Exclusion criteria: Dissatisfaction for continued study, Mental retardation, dementia, discontinue treatment before session 4, Delirium during treatment Prohibition of acetyl cholinesterase inhibitors because of a cardiac disorder, chronic obstructive pulmonary disease, Acute peptic ulcer, Lack of literacy

##### Intervention groups

Intervention group received Donepezil with dose of 5 mg per day at the start of study to 1 month after the end of electroconvulsivetherapy and placebo group received placebo with the same color and shape like Donepezil

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

ECT(electroconvulsivetherapy)

##### IRCT registration information

IRCT registration number: **IRCT20180623040193N1**

Registration date: **2018-07-09, 1397/04/18**

Registration timing: **retrospective**

Last update: **2018-07-09, 1397/04/18**

Update count: **0**

##### Registration date

2018-07-09, 1397/04/18

##### Registrant information

##### Name

Elham Zarean

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3222 0016

##### Email address

e.zarean@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-06-22, 1396/04/01

##### Expected recruitment end date

2018-03-20, 1396/12/29

##### Actual recruitment start date

2017-07-29, 1396/05/07

##### Actual recruitment end date

2018-03-20, 1396/12/29

**Trial completion date**  
empty

**Scientific title**  
Evaluation of Donepezil effectiveness on prevention of cognitive impairment caused by electroconvulsivetherapy (ECT) in mood disorder patients

**Public title**  
Donpezil efficacy in prevention of cognitive impairment induced by electroconvulsivetherapy

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age 15-65 years old  
Diagnosis of Major depressive disorder by a psychiatrist  
Diagnosis of bipolar disorder by a psychiatrist  
Prescribing at least four session of electroconvulsivetherapy  
inform consent  
**Exclusion criteria:**  
Dissatisfaction for continued study  
Mental retardation  
dementia  
discontinue treatment before session 4  
Delirium during treatment  
Prohibition of acetyl cholinesterase inhibitors because of a cardiac disorder  
chronic obstructive pulmonary disease  
Acute peptic ulcer  
Lack of literacy

**Age**  
From **15 years** old to **65 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **94**  
Actual sample size reached: **94**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patient were randomly allocated to either intervention or controlled group using random number generator software

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Participant, Care provider(nurses), Investigator,data collectors and Outcome assessor are blinded.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**

1  
**Registry name**  
**Secondary trial Id**  
**Registration date**  
empty

2  
**Registry name**  
**Secondary trial Id**  
**Registration date**  
empty

3  
**Registry name**  
**Secondary trial Id**  
**Registration date**  
empty

## Ethics committees

1  
**Ethics committee**  
**Name of ethics committee**  
Ethics committee of SHahrekord University of Medical Sciences  
**Street address**  
Kashani Ave,SHahrekord university of medical science  
**City**  
SHahrekord  
**Province**  
Chahar-Mahal-va-Bakhtiari  
**Postal code**  
۸۸۱۵۷۱۳۴۷۱  
**Approval date**  
2017-07-29, 1396/05/07  
**Ethics committee reference number**  
IR.SKUMS.REC.396.49

## Health conditions studied

1  
**Description of health condition studied**  
Cognitive impairment  
**ICD-10 code**  
**ICD-10 code description**

## Primary outcomes

1  
**Description**  
cognitive impairment  
**Timepoint**  
before start of electroconvulsivetherapy, before session 4 and one month after the end of electroconvulsivetherapy  
**Method of measurement**

Addenbrooke's Cognitive Examination-C, mini mental status examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: consumption of 5 mg per day of Donepezil(Produced in Ramofarmin Pharmaceutical Company) before the start of electroconvulsivetherapy to one month after the end of it

#### Category

Prevention

### 2

#### Description

Control group: Daily consumption of placebo tablet (produced in Raha Pharmaceutical Company with the same shape and color with Donpezil) before starting electroconvulsivetherapy to one month after the end of it

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hajar hospital

##### Full name of responsible person

Elham Zarean

##### Street address

Weman and men admission wards of psychiatry, Hajar hosp, Parastar Ave, SHahre-kord

##### City

Shahre-kord

##### Province

Chahar-Mahal-va-Bakhtiari

##### Postal code

8816758915

##### Phone

+98 38 3222 0016

##### Email

e.zarean@skums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahre-kord University of Medical Sciences

##### Full name of responsible person

Kamal Solati

##### Street address

Deputy of research and technology, Kashani Ave, Shahrekord

##### City

Shahre-kord

##### Province

Chahar-Mahal-va-Bakhtiari

##### Postal code

8815713471

##### Phone

+98 38 3333 0061

##### Email

kamal\_solati@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

##### Full name of responsible person

Elham Zarean

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Psychiatrics

##### Street address

Department of Psychiatry, Hajar Hosp, parastar Ave, SHahre-kord

##### City

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##### Email

ezarean@gmail.com

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Elham Zarean

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Elham Zarean

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**Fax**

**Email**

ezarean@gmail.com

## **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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

data collected using questioners

**When the data will become available and for how long**

starting 6 months after publication for 3 months

**To whom data/document is available**

only available for people working in academic institutions

**Under which criteria data/document could be used**

Doing similar research

**From where data/document is obtainable**

email

**What processes are involved for a request to access data/document**

after receiving request via email, evaluation will be done

**Comments**