

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

SHahre-kord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816758915

Phone

+98 38 3222 0016

Fax

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

Street address

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

City

SHahre-kord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816758915

Phone

+98 38 3222 0016

Fax**Email**

ezarean@gmail.com

Person responsible for updating data

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

SHahre-kord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816758915

Phone

+98 38 3222 0016

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