Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Evaluation of the Donepezil and Rivastigmine co – administration on the cognitive deficits induced by EcT: A Randomized Double Blind Clinical Trial

Protocol summary

Study aim
Comparison of cognitive function in patients receiving Donpezil, Rivastigmine, and control group before and after receiving ECT

Design
Randomized Double Blind Clinical trail with control group

Settings and conduct
60 patients aged 18-60 years old admitted to the psychiatric department of Golestan Hospital who had been subjected to ECT were randomly divided into three groups of 20 people. The first group received Rivastigmine, the second group received Donepezil, and the third group received placebo. All drugs and placebos are similar in shape, color and odor. The patients and the executor of plan unaware of which of the people in the three groups receive medication or placebo.

Participants/Inclusion and exclusion criteria
Inclusive Criteria: Patients between 18 and 60 ages Patients with mood and Psychotic disorders Candidate for treatment with 6 to 12 ECT sessions Exclusive Criteria: Neurological and Somatic Diseases and cognitive impairments, Pregnancy and Breast feeding Having ECT treatment in past 6 months Having treatment with Rivastigmine and Donepezil in past 3 months MMSE<24 Substance and Alcohol use

Intervention groups
Giving rivastigmine capsule to the first intervention group, donepezil tablet to the second intervention group, and Placebo to the control group

Main outcome variables
Cognitive Function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171229038124N1**
Registration date: **2018-08-04, 1397/05/13**
Registration timing: **retrospective**

Last update: **2018-08-04, 1397/05/13**
Update count: **0**

Registration date
2018-08-04, 1397/05/13

Registrant information

Name
Masoumeh Nazarinasab

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3374 3038

Email address
nazarinasab-m@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-11-22, 1396/09/01

Expected recruitment end date
2018-06-21, 1397/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Donepezil and Rivastigmine co – administration on the cognitive deficits induced by EcT: A Randomized Double Blind Clinical Trial

Public title
Evaluation of the Donepezil and Rivastigmine co – administration on the cognitive deficits induced by EcT: A Randomized Double Blind Clinical Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Schizophrenia Disorder Schizoaffective Disorder Bipolar Mood Disorder Major Depressive Disorder ECT 6-12 Sessions
Exclusion criteria:
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Table of Random Number
Blinding (investigator's opinion)
Double blinded
Blinding description
1. The participants, while aware that the placebo and two Donepezil and Rivastigmine drugs were used in this study, were unaware of the medicine being given to them. 2. In this study, the researcher does not know how each participant is undergoing treatment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
Golestan Hospital, Ahvaz Joundishapour University of Medical Sciences, Golestan
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Approval date
2017-11-11, 1396/08/20
Ethics committee reference number
IR.AJUMS.REC.1396.609

Health conditions studied

1

Description of health condition studied
EcT in patients with Mood Disorders
ICD-10 code
F31
ICD-10 code description
Bipolar affective disorder

Primary outcomes

1

Description
Evaluation of cognitive function by MMSE
Timepoint
In the first, middle and end of the period of ECT Therapy
Method of measurement
MMSE

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Tablet Donepezil 5 mg daily for 2 weeks
Category
Other

2

Description
Intervention group: Cap Rivastigmine 1.5 mg twice a day for one week and 3 mg twice a day until the end of study
Category
Other

3

Description
Control group: Placebo
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Golestan Hospital

Full name of responsible person
Masoumeh Nazarinasab

Street address
Golestan Hospital, Ahvaz Joundishapour University of Medical Sciences, Golestan

City
Ahvaz

Province
Khouzestan

Postal code
6135733118

Phone
+98 61 3374 3038

Email
nazarinasab-m@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Dr Mohammad Badavi

Street address
Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences, Golestan

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3336 1984

Email
info@ajums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Masoumeh Nazarinasab

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Golestan Hospital, Ahvaz Joundishapour University of Medical Sciences, Golestan

City
Ahvaz

Province
Khouzestan

Postal code
6135733118

Phone
+98 61337430011

Email
Nazarinasab-m@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Masoumeh Nazarinasab

Position
Assistant professor

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City
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Province
Khouzestan

Postal code
6135733118

Phone
+98 61337430011

Email
Nazarinasab-m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Masoumeh Nazerinasab

Position
Assistant professor
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Golestan Hospital, Ahvaz Joundishapour University of Medical Sciences, Golestan
City
Ahvaz
Province
Khouzestan
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6135733118
Phone
+98 61337430011
Email
Nazarinasab-m@ajums.ac.ir

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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Some of the data could be shared.
When the data will become available and for how long
It would be available 6 months after publication of the results
To whom data/document is available
University Researchers
Under which criteria data/document could be used
For research and treatment issues
From where data/document is obtainable
To published article
What processes are involved for a request to access data/document
Journal's website
Comments