Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Donepezil on cognitive disturbances due to Selective Serotonine reuotake Inhibitor drugs in major Depressive disorders

Protocol summary

Summary

Objective: The effect of Donepezil on cognitive disturbances due to Selective Serotonine reuotake Inhibitor drugs in major Depressive disorders. type of study: This study is a double blind randomized controlled trial. 76 patients were enrolled based on inclusion and exclusion criteria, and then by a table of random numbers and without the knowledge of the type of intervention, were assigned to two groups. Study population: all patients with Major Depressive disorder from 06.22.2014 to 12.22.2014 were admitted to the Taft psychiatric clinic and clinic Khatamolanbiyae Yazd. Inclusion criteria: patients in the age range 30 to 40 years, Complete the consent form, with Major Depression according to the text of the revised fourth edition of Diagnostic and Statistical Manual of Mental Disorders, treated with selective Serotonin reuptake inhibitors, two months after receiving antidepressant assessment exam Montreal is less than 26. Exclusion criteria: At the same time suffering from major depression and other mental disorders. At the same time suffering from major depression and a physical disorder with features of cognitive impairment including Alzheimer's or other degenerative neurological disorders, head injuries or Hypothyroidism. Concomitant use of Anticholinergic agents, nervous system depressant drugs. Intervention: donepezil 0.5 mg tablet daily for 2 months in the intervention group and donepezil placebo in the control group, after 2 months of using the Montreal Cognitive Assessment Test are evaluated. The consequence: Major Depression

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092824236N1**
Registration date: **2016-07-09, 1395/04/19**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-07-09, 1395/04/19

Registrant information

Name
Fatemeh Hosseini
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Donepezil on cognitive disturbances due to Selective Serotonine reuotake Inhibitor drugs in major Depressive disorders

Public title

The effect of Donepezil on Depression

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients in the age range 30 to 40 years, Complete the consent form, with major Depression according to the text of the revised fourth edition of Diagnostic and Statistical Manual of Mental Disorders, Treated with selective Serotonin reuptake inhibitors, Two months after receiving Antidepressant assessment exam Montreal is less than 26. Exclusion criteria: At the same time suffering from major Depression and other mental disorders. At the same time suffering from major Depression and a physical disorder with features of cognitive impairment including Alzheimer or other degenerative neurological disorders, head injuries or Hypothyroidism. Concomitant use of Anticholinergic agents and nervous system Depressant drugs
Age
From **30 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **76**
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
Ethic Committee of Shahid Sadoughi University of Medical Sciences
Street address
Shahid Sadoughi University of Medical Sciences, Bahonar Sq, Yazd
City
Yazd
Postal code
Approval date
2015-05-22, 1394/03/01
Ethics committee reference number
IR.SSU.MEDICINE.REC.1394.374

Health conditions studied

1

Description of health condition studied
Majore Depressive
ICD-10 code
F32.3
ICD-10 code description
Severe depressive episode with psychotic symptoms

Primary outcomes

1

Description
Major Depressive Disorder
Timepoint
2 months after drug consumption
Method of measurement
Montreal Cognitive assessment test

Secondary outcomes

1

Description
Drug side effects
Timepoint
2 months after drug consumption
Method of measurement
Examination and test results

Intervention groups

1

Description
Intervention group: Donepezil 0.5 mg tablet daily for 2 months
Category
Treatment - Drugs

2

Description
In the control group: Placebo Donepezil daily for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taft psychiatric Clinic
Full name of responsible person
Fateme Hosseini
Street address

Psychiatric clinic, Taft
City
Taft

2

Recruitment center
Name of recruitment center
Khatamolanbiyae Clinic
Full name of responsible person
Fateme Hosseini
Street address
Khatamolanbiyae clinic, Taleghani Blv, Yazd
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Amir Houshang Mehrparvar
Street address
Shahid Sadoughi University of Medical Sciences, Bahonar Sq,Yazd
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Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of Shahid Sadoughi 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