

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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

Country

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

Major 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
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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
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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

Contact

Name of organization / entity
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Person responsible for updating data

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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