

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluating the efficacy of adding Donepezil to a selective serotonin re-uptake inhibitor (Sertraline) in the treatment of major depressive disorder

Protocol summary

Summary

This study is a randomized double blind clinical trial which is being done in Sari at 2014-2015. The study is to determine the effects of adding Donepezil to Sertraline in the treatment of Major Depressive Disorder and it is scheduled to assess the effects of this addition on memory and depression. Forty outpatients with Major Depressive Disorder based on DSM-IV-TR will be included if they have no history of serious medical or psychiatric disorders other than depression. Patients will be randomly allocated to Donepezil (5 mg) or placebo added to Sertraline. At baseline, Wechsler Memory Scale and the Hamilton Depression Rating Scale will be done. During 3 months of treatment symptoms will be checked by Hamilton Depression Rating Scale every four weeks and Wechsler memory scale at the end of study and three months later. Side effects will be assessed with direct questions and observing main complications

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031011885N2**
Registration date: **2014-12-01, 1393/09/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-01, 1393/09/10

Registrant information

Name

Samaneh Farnia

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3328 5659

Email address

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2014-07-10, 1393/04/19

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of adding Donepezil to a selective serotonin re-uptake inhibitor (Sertraline) in the treatment of major depressive disorder

Public title

Efficacy of Donepezil in the treatment of Major Depressive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Entry: All outpatients with Major Depressive Disorder based on DSM-IV-TR in the age range of 25-55 year old who refer to psychiatric clinic in Zare hospital or Tooba clinic. Exclusion criteria: Catatonia; Acute suicidal idea; Major past medical history; Endocrine diseases; Chronic cardiovascular diseases; Respiratory diseases; Hepatic

failure; Renal failure; Active peptic ulcer, Acute infectious diseases; Malignancies; Neurologic disorders; Axis I psychiatric disorders except of Major depressive disorder; Axis II psychiatric disorders; Family history of bipolar disorder; Concomitant use of psychiatric drugs except for Antidepressants; Outside the age range of 25-55; refuse to participate in the study; Pregnancy, Breastfeeding; Lack of contraception in women of childbearing age.

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

This is a randomized double-blind controlled study. The participants and assessor are aware of neither drugs nor placebo. The block randomization method is used .

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mazandaran University of Medical Sciences

Street address

moallem square

City

sari

Postal code**Approval date**

2014-07-09, 1393/04/18

Ethics committee reference number

93/4/18

Health conditions studied**1****Description of health condition studied**

Major Depressive Disorder

ICD-10 code

f32.2

ICD-10 code description

Sever Depressive Episode Without Psychotic Symptoms

Primary outcomes**1****Description**

Memory

Timepoint

Before intervention,End of intervention,3months after ending intervention

Method of measurement

With wechsler memory scale

2**Description**

Depression

Timepoint

Before intervention,Every month for three months after beginning intervention,3months after ending intervention

Method of measurement

With hamilton depression rating scale

Secondary outcomes**1****Description**

Side effects of drugs

Timepoint

1st,2st.3st month after intervention and three month after ending intervention

Method of measurement

By filling a checklist of drug side effects

Intervention groups**1****Description**

Intervention group: Twenty patients receive donepezil tablet 5 miligram/daily plus sertraline tablet 50 -100 miligram/day given orally up to three months.

Category

Treatment - Drugs

2**Description**

Control group: Twety patients receive placebo .It is made similar to donepezil tablet by pharmaceutical industry experts.The placebo is added to sertraline. It is given orally up to three months .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare hospital-Psychiatry clinic

Full name of responsible person

Dr.Samaneh farnia

Street address

Zare hospital-Neka road

City

Sari

2

Recruitment center

Name of recruitment center

Tooba center psychiatry clinic

Full name of responsible person

Dr.Samaneh farnia

Street address

Khazar square,Tooba center

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati MD

Street address

Moallem street-Moallem square-Vice chancellor for research

City

Sari

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, Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Seid Davood Hosseini Talari

Position

Psychiatrist Assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Dr.Samaneh farnia

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Fax

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Web page address

Person responsible for updating data

Contact

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