

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Memantine augmentation of escitalopram in treatment of executive function among patients with OCD, a Double-blind placebo controlled randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of treatment with escitalopram and memantine with escitalopram and placebo in improving the executive function and symptoms of patients with obsessive-compulsive disorder

Design

Double blind, placebo controlled, randomized clinical trial with parallel group design of 60 patients

Settings and conduct

To conduct this study, a sample of 60 people is needed which are selected from the patients attending Ibn Sina Hospital and Clinic and Professor Mohrari in Shiraz. The patients are informed about the study either in person or by phone. The conditions and the procedure are explained to them and their consent is obtained. Patients who meet the conditions for entering the study are divided into two groups of 30 people and receive the drugs according to the descriptions. In weeks 0, 4, 8, 12 and 16, patients complete the Y-BOCS questionnaire to evaluate their treatment process. In weeks 0 and 16, the BDEFS questionnaire is completed by the patients to check the executive function. In weeks 4, 8, 12 and 16, the side effects of the drug are evaluated by a questionnaire.

Participants/Inclusion and exclusion criteria

Diagnosis of Obsessive compulsive disorder based on Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-V) Criteria Yale - Brown Obsessive Compulsive Scale (Y-BOCS) score equal or more than 18

Intervention groups

In the control group, escitalopram starts with a dose of 5 mg per day and after 4 weeks the dose is increased to 10 mg per day and continues this way until the end of 16 weeks. This group receives placebo along with escitalopram. Intervention group receives escitalopram in the same way as the control group. This group receives memantine at a dose of 10 mg per day along

with escitalopram.

Main outcome variables

Yale - Brown Obsessive Compulsive Scale score Barkley Deficits in Executive Functioning Scale score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211118053093N5**

Registration date: **2023-06-25, 1402/04/04**

Registration timing: **prospective**

Last update: **2023-06-25, 1402/04/04**

Update count: **0**

Registration date

2023-06-25, 1402/04/04

Registrant information

Name

Kimia Sahraian

Name of organization / entity

Eghlid Higher Education Center

Country

Iran (Islamic Republic of)

Phone

+98 71 3630 3886

Email address

leilarazeghian1366@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Memantine augmentation of escitalopram in treatment of executive function among patients with OCD, a Double-blind placebo controlled randomized clinical trial

Public title

Memantine in treatment of OCD

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

OCD diagnosis based on DSM-V criteria Y-BOCS score equal or more than 18

Exclusion criteria:

Drug abuse Pregnancy Medical problems

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

After gathering the patients randomization will be performed by main researcher by using random number table. The patients will be divided into 2 groups which everyone contains 30 patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants do not know which group they are in. The data analyser does not know which group it is analysing. The number of weeks of drug use is the same, so the patient is blinded to the type of treatment. Data analysis is given only data and does not know what treatment was done for which group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Kilometer 13 of Shiraz-Isfahan highway, Ostad Mohrari Hospital

City

Shiraz

Province

Fars

Postal code

71441-13331

Approval date

2023-06-10, 1402/03/20

Ethics committee reference number

IR.SUMS.MED.REC.1402.093

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

Obsessive-Compulsive Disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

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

Yale-Brown Obsessive Compulsive Scale score

Timepoint

Week 0, 4, 8, 12, and 16

Method of measurement

Yale-Brown Obsessive Compulsive Scale questionnaire

2**Description**

Barkley Deficits in Executive Functioning Scale score

Timepoint

Week 0 and 16

Method of measurement

Barkley Deficits in Executive Functioning Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In the control group, escitalopram starts with a dose of 5 mg per day and after 4 weeks the dose is increased to 10 mg per day and continues this way until the end of 16 weeks. This group receives placebo along with escitalopram.

Category

Treatment - Drugs

2

Description

Intervention group: receives escitalopram in the same way as the control group. This group receives memantine at a dose of 10 mg per day along with escitalopram.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Professor Moharari Psychiatric Hospital

Full name of responsible person

Leila RazeghianJahromi

Street address

13 km Shiraz-Isfahan, Ostad Mohrari Hospital

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+98 71 3260 5701

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leilarazeghian1366@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Leila RazeghianJahromi

Street address

13 km Shiraz-Isfahan, Ostad Mohrari Hospital

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Leila Razeghian Jahromi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

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Shiraz University of Medical Sciences

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available