

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The Efficacy of Memantine as Adjunctive Therapy in Obsessive Compulsive Disorder A Double blind Placebo controlled Randomized Trial

Protocol summary

Study aim

Comparison of treatment effect of Memantine plus Sertraline with Placebo and Setraline on OCD patients

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks. To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who assess patients in follow-up visits will be unaware if each number belongs to which groups.

Settings and conduct

OCD outpatients who come to psychiatric clinics of Iran University of Medical Sciences and Tabriz University of Medical Sciences will be recruited.

Participants/Inclusion and exclusion criteria

Patients who meet DSM-5 criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. They should be 18-65 years old and sign consent form. they should not be treated by any psychiatric interventions for last 6 weeks. If they show any other important mental condition or suicidal thought, neurological deficit, will exclude from study. They will evaluate for cardiac, liver, kidney, pregnancy, lactation and mental retardation before entrance and any mentioned conditions will cause exclusion from study.

Intervention groups

Memantine plus Setraline and Placebo plus Sertraline

Main outcome variables

Severity of obsessive-compulsive disorder

General information

Reason for update

Acronym

OCD

IRCT registration information

IRCT registration number: **IRCT20170123032145N4**

Registration date: **2019-10-04, 1398/07/12**

Registration timing: **prospective**

Last update: **2019-10-04, 1398/07/12**

Update count: **0**

Registration date

2019-10-04, 1398/07/12

Registrant information

Name

Mohammadreza Shalbfan

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 1665

Email address

shalbfan.mr@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Memantine as Adjunctive Therapy in

Obsessive Compulsive Disorder A Double blind Placebo controlled Randomized Trial

Public title

Memantine for treatment of Obsessive-Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who meet DSM-5 criterion for OCD and they achieve more than 21 for Yale-Brown Obsessive Compulsive Scale are suitable for study. They should be 18-65 year old and sign consent form

Exclusion criteria:

They should not be treated by any psychiatric interventions for last 6 weeks. If they show any other important mental condition or suicidal thought, neurological deficit, will exclude from study. They will be evaluated for cardiac, liver, kidney, pregnancy, lactation and mental retardation before entrance and any mentioned conditions will cause exclusion from study.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be used in this trial based on balance block randomization and by 4:1 blocks

Blinding (investigator's opinion)

Triple blinded

Blinding description

To do study with concealment, table of block will be used by one of researchers, other than interviewer and who assess patients in follow-up visits, to write number of each participants on box of additional drugs. Therefore, all of patients, interviewer and who evaluates patients in follow-up visits will be unaware if each number belongs to which groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-09-21, 1398/06/30

Ethics committee reference number

IR.IUMS.REC.1398.640

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**

Severity of obsessive-compulsive disorder

Timepoint

Weeks: 0, 4, 8 and 12

Method of measurement

Yale-Brown Obsessive Compulsive Scale(YBOCS)

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

Working Memory

Timepoint

Weeks: 0, 4, 8, 12

Method of measurement

Wisconsin Test

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

Intervention group: : Sertraline(Tab) up to 200 mg/day

plus Memantine (Tab) 10mg twice per day for 12 weeks

Category

Treatment - Drugs

2**Description**

Control group: Sertraline(Tab) up to 200 mg/day plus placebo(Tab) twice per day for 12 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Iran Psychiatric Hospital

Full name of responsible person

Dr Mohammadreza Shalbafan

Street address

Tehran-Karaj Highway 7 km

City

Tehran

Province

Tehran

Postal code

1398913151

Phone

+98 21 4450 3395

Email

Shalbafan.mr@iums.ac.ir

Web page address

<http://iph.iums.ac.ir/>

2**Recruitment center****Name of recruitment center**

Tehran Psychiatric Institute

Full name of responsible person

Dr Mohammadreza Shalbafan

Street address

Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

+98 21 6655 1665

Email

Shalbafan.mr@iums.ac.ir

3**Recruitment center****Name of recruitment center**

Razi hospital

Full name of responsible person

Dr Mehrdad Ghaemmaghami

Street address

Bakeri Blvd.

City

Tabriz

Province

East Azarbaijan

Postal code

5167846184

Phone

+98 41 3380 4486

Email

Shalbafan.mr@iums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Abbas Motavalian

Street address

Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

+98 21 6650 6862

Email

mhrc@iums.ac.ir

Web page address

<http://mhrc.iums.ac.ir/>

Grant name

Young Assistant Professors grant

Grant code / Reference number

15669

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

Yes

Title of funding source

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr Mohammadreza Shalbafan
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue
City
Tehran
Province
Tehran
Postal code
1445613111
Phone
+98 21 6655 1665
Email
shalbafa.mr@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Mohammadreza Shalbafan
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue
City
Tehran
Province
Tehran
Postal code
1445613111
Phone
+98 21 6655 1665
Email
shalbafa.mr@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Shalbafan
Position
Psychiatrist/ Assistant Prof.
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Iran Psychiatry Hospital, Tehran-Karaj Exp.way 7th Km, Tehran
City
Tehran
Province
Tehran
Postal code
1398913151
Phone
+98 21 4452 5615
Fax
+98 21 6655 1665
Email
shalbafan.mr@iums.ac.ir
Web page address

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

Not applicable

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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data about main outcome of study will be published

When the data will become available and for how long

2022

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

For scientific goals

From where data/document is obtainable

shalbafan.mr@iums.ac.ir Dr Mohammadreza Shalbafan

What processes are involved for a request to access data/document

Sending an E-mail and reason of request

Comments