Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

The effect of Memantine on the severity of symptoms and brain function in patients with Obsessive-Compulsive Disorder (OCD) : An Event Related Potential (ERP) study

Protocol summary

Study aim
The effect of Memantine on the severity of symptoms and brain function in patients with obsessive-compulsive disorder, a study using event-dependent potentials (ERP)

Design
A randomized clinical trial, on 50 patients (two groups of 25 people), block randomization (via randomization site), parallel groups, double-blind, phase 3

Settings and conduct
This is a randomized Triple-blind study.This study will be performed on 50 patients with obsessive-compulsive disorder, who will be referred to outpatient clinical of EbneSina Hospital. Patients will be evaluated separately by a psychiatrist. The severity of obsessive-compulsive disorder in these patients will be assessed at the beginning of the study by interviewing a psychiatrist using the Yale Brown Obsessive-Compulsive Disorder (Y-BOCS) scale , who meet the inclusion and exclusion criteria, will enter the study after obtaining informed consent.The results of the psychiatrist's interview with the patient and the evaluation of (Y-BOCS) scale will be recorded in a special questionnaire for each patient at the beginning of the study (before the intervention) and 1 month, 2 months and 3 months after the interventio

Participants/Inclusion and exclusion criteria
1)OCD patients who have been treated with high doses of SSRI for at least 8 weeks but have a Y-BOCS index score higher than 15. (High doses of SSRI includ: Sertraline 200mg/day, Paroxetine 60mg/day, Fluoxetine 80mg/day and Fluvoxamine mg/day) 2)subjects aged 18 to 60 years 3) Obtaining the patient's informed consent

Intervention groups
group1: high dose of SSRI + placebo group.group2: high dose of SSRI + memantine (20 mg/day)

Main outcome variables
(Y-BOCS) YALE-BROWN OBSESSIVE COMPULSIVE SCALE

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130518013359N5**
Registration date: **2021-12-18, 1400/09/27**
Registration timing: **prospective**

Last update: **2021-12-18, 1400/09/27**
Update count: **0**

Registration date
2021-12-18, 1400/09/27

Registrant information

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Name of organization / entity
Mashhad University Of medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2024-09-20, 1403/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title

The effect of Memantine on the severity of symptoms and brain function in patients with Obsessive-Compulsive Disorder (OCD) : An Event Related Potential (ERP) study

Public title

The effect of Memantine on the severity of symptoms and brain function in patients with Obsessive-Compulsive Disorder (OCD) : An Event Related Potential (ERP) study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with obsessive-compulsive disorder who have been treated with high doses of SSRI for at least 8 weeks but whose Y-BOCS index is higher than cut-off 15. People aged 18 to 60 years Obtain patient informed consent

Exclusion criteria:

Pregnancy or breastfeeding Using serotonergic drugs other than SSRIs Use of NMDA receptor antagonists other than memantine Psychotic and bipolar disorders (based on DSM-5 criteria) Major Depressive Disorder (Based on DSM-IV-TR Criteria) Other anxiety disorders (such as panic disorder, post-traumatic stress disorder (PTSD), general anxiety disorder (GAD) Abuse or dependence on drugs or alcohol Liver dysfunction (LFT> 3ULN) Kidney dysfunction (GFR <60 ml / kg / min) Thyroid Disorders (Based on Thyroid Function Test) History of seizures Cognitive-behavioral therapy

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is done using the site https://www.sealedenvelope.com. Each block has 8 members and for example can be as follows: [AABBCCDD], [ABCDABCD], [AABBDCD],... Codes A, B, C, D are assigned randomly to the intervention groups and the control group. The aforementioned site randomly selects 9 blocks from all eight-member blocks so that 50 patients can be included in the study.The allocation concealment method is by use of opaque sealed envelopes with random sequences obtained from the random allocation step.

Blinding (investigator's opinion)

Triple blinded

Blinding description

As our data are collected step by step and patients are gradually included in the study, concerning the time of inclusion and at the beginning of inclusion according to the sequence obtained in the randomization stage, the patients will be assigned to either control groups or interventions groups. These codes are provided to the researcher present in the physician's office. It is worth mentioning that this researcher should be fully aware of the type of code. The researcher is also provided with the medications in terms of the assigned number (D or C or B or A) and is fully aware of the fact that which medication is Memantine or placebo, as well. (This researcher is engaged neither in prescribing and evaluating the treatments, nor in analyzing data, and is exclusively responsible for maintaining codes and delivering medications to the patients based on a random code allocated by the physician.) The assigned code is recorded in the CRF form. Initially, the prepared codes are given to the researcher, if the inclusion criteria are fulfilled and based on the codes, the patient is randomly included in one group. The allocated code is documented in the CRF form and the researcher takes the drugs or placebo into account based on the code assigned to the patient. After taking either the medication or placebo for three months by the patients, in the clinic of Ebn-e-Sina Hospital, the patients are appraised by a physician who has no idea which drug the patients have received and is only aware of the assigned codes and then carries out the appropriate evaluations. After documentation, the results in the form of codes are provided to the person who performs the data analysis. The data analysis is performed while the data analyzer has no information about the type of the taken medication, and all confidential information is recorded and stored without mentioning the patient's name

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ethic committee of Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah street

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Razavi Khorasan

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91375-345

Approval date

2021-10-12, 1400/07/20

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.578

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

Evaluation of the effect of memantine in comparison with placebo on reducing the severity of symptoms in patients with obsessive-compulsive disorder based on (Y-BOCS) YALE-BROWN OBSESSIVE COMPULSIVE SCALE.

Timepoint

Before intervention and 1 month, 2 months and 3 months after intervention.

Method of measurement

Yale–Brown Obsessive Compulsive Scale

Secondary outcomes

1

Description

Comparison of quantitative electroencephalographic (QEEG) changes in different groups

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Quantitative Electroencephalogram

Intervention groups

1

Description

Intervention group: Patients are selected from outpatients who visit the clinic of EbneSina Hospital. In the intervention group, patients diagnosed with obsessive-compulsive disorder, who meet the inclusion and exclusion criteria, will randomly add one of the following four interventions to their high-dose (SSRI) regimen. (This study will be performed on patients with obsessive-compulsive disorder who have been on high doses of SSRI for at least 8 weeks but have a Y-BOCS index score higher than 15) The severity of symptoms of obsessive-compulsive disorder will be assessed using the Yale Brown Obsessive-Compulsive Disorder Scale before intervention and 1 month, 2 months and 3 months after intervention. Quantitative electroencephalography (QEEG) will be done before the intervention and 3 months after the intervention. Intervention group1: high dose of SSRI (High doses of SSRIs include sertraline: maximum 200mg / day, paroxetine: maximum 60mg / day, fluoxetine: maximum 80mg / day, fluvoxamine: maximum 300mg / day) + memantine (20 mg/day). The main medication, Memantine, is purchased from Sobhan pharmaceutical company.

Category

Treatment - Drugs

2

Description

Control group: high dose of SSRI + placebo The placebo tablet contains all the ingredients of the main pill and only lacks the active ingredient Memantine, and will receive 4 tablets a day for 3 months in addition to the standard treatment regimen for obsessive-compulsive patients. The placebo tablet, which is similar to the main medication in terms of shape and color is made in Mashhad School of Pharmacy in accordance with the principles of GLP.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebn'e Sina Hospital, outpatient clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Sadjadi alireza

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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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
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Title and more details about the data/document
all collected deidentified IPD

When the data will become available and for how

long

starting 6 months after publication

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

only available for people working in academic institutions and there is not another condition

From where data/document is obtainable

sadjadia@mums.ac.ir

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

sadjadia@mums.ac.ir

Comments