Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of Memantine’s Effect on Symptom Characteristics, Neuro-Cognitive Functioning and Neuronal Networks Organization in Patients with Obsessive-Compulsive Disorder: A Randomized, Double-blind, Placebo-Controlled Clinical Trial with Parallel Design

Protocol summary

Study aim

Evaluation of Memantine’s Effect on Symptom Characteristics, Neuro-Cognitive Functioning and Neuronal Networks Organization in Patients with Obsessive-Compulsive Disorder

Design

Randomized, placebo-controlled, double-blind clinical trial

Settings and conduct

This study will be conducted in a randomized double-blind clinical trial setting at Jami Neuropsychiatry Clinic and National Brain Mapping Laboratory, within the determined temporal duration.

Participants/Inclusion and exclusion criteria

Patients with Obsessive-Compulsive Disorder/ Definitive diagnosis of obsessive-compulsive disorder based on the psychiatrist assessment and its confirmation according to SCID-5 (Structured-Clinical Interview for DSM5) by the clinical psychologist, Y-BOCS Score equal or more than 16 for obsessions and compulsions or equal or more than 10 only for obsessions or compulsions, within the age range of 18-50 years old will be included. Subjects with major depressive disorder, bipolar disorder, personality disorder, and schizophrenia in a way that questions the diagnose of obsessive-compulsive disorder, past or current drug/alcohol abuse or dependence, previous exposure to any kind of psychotropic medication (benzodiazepines, antipsychotics, antidepressants, stimulants, mood stabilizers), past or current neurological disorders (Seizures, Epileptic Syndromes, Head Trauma, Stroke, Loss of consciousness), and other severe internal and surgical disorders will not be included.

Intervention groups

Intervention group: Memantine. Control group: Placebo

Main outcome variables

Symptoms (Obsession and Compulsions) severity; Response rate to Memantine treatment.

General information

Reason for update

The reason for the updating is to make changes to the grouping of the clinical trial, such that, in the previous model, two groups were considered, but in the current edited mode, it changed to three groups. Respectfully, the reason for this change request is explained below. After a preliminary statistical analysis and review of newer literature, adding a group of healthy individuals to compare the baseline conditions more accurately and to compare changes in secondary outcome variables seemed necessary.

Acronym

IRCT registration information

IRCT registration number: **IRCT20140120016280N4**
Registration date: **2020-07-30, 1399/05/09**
Registration timing: **prospective**

Last update: **2022-01-15, 1400/10/25**
Update count: **3**

Registration date

2020-07-30, 1399/05/09

Registrant information

Name

Mahmoudreza Hadjighassem

Name of organization / entity

TUMS

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-09-10, 1399/06/20
Expected recruitment end date
2021-07-23, 1400/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Memantine’s Effect on Symptom Characteristics, Neuro-Cognitive Functioning and Neuronal Networks Organization in Patients with Obsessive-Compulsive Disorder: A Randomized, Double-blind, Placebo-Controlled Clinical Trial with Parallel Design

Public title
Evaluation of Memantine’s Effect on Symptom Characteristics in Patients with Obsessive Compulsive Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of obsessive-compulsive disorder based on the psychiatrist assessment and its confirmation according to SCID-5 (Structured-Clinical Interview for DSM5) by the clinical psychologist Y-BOCS Score equal or more than 16 for obsessions and compulsions or equal or more than 10 only for obsessions or compulsions. Being in The age range of 18-50 IQ level more than 80 based on Wechsler Adult Intelligence Scale Signing written informed consent
Exclusion criteria:
Subjects with major depressive disorder, bipolar disorder, personality disorder, and schizophrenia in a way that questions the diagnose of obsessive-compulsive disorder. Pregnancy, lactation or the imminent possibility of either of these cases or use of birth control methods for female subjects (these items will be assessed by the validated urine tests) Past or current drug/alcohol abuse or dependence (these items will be assessed by the urine toxicology tests) Previous exposure to any kind of psychotropic medication (benzodiazepines, antipsychotics, antidepressants, stimulants, mood stabilizers) Previous exposure to at least 8 sessions of structured psycho-therapeutic courses Past history or current existence of neurological diseases (seizures, epilepsy syndromes, history of trauma, stroke, loss of consciousness) and other severe internal and surgical disorders Presence of any contraindication to MRI scanning, including metal implants or claustrophobia. Metal implants, pacemaker, other metal (e.g. shrapnel or surgical prostheses) or paramagnetic objects contained within the body which may present a risk to the subject or interfere with the MR scan, as determined in consultation with a neuroradiologist and according to the guidelines set forth in the following reference book commonly used by the neuroradiologists:"Guide to MR procedures and metallic objects", F. G. Increase in liver enzymes SGOT and SGPT more than threefold compared with baseline levels.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization process will be done using permuted block randomization with blocks in size 4. Regarding determined sample size 48و, quadratic blocks will be produced using the online website: www.sealedenvelope.com. Unique code will be used to apply the allocation concealment to drug boxes, and the code will also be generated by the software. As each individual enters the study based on the sequence generated, the drug box in which the code in question is assigned will be assigned to the individual.
Blinding (investigator's opinion)
Double blinded
Blinding description
Since the current study will be performed within the neuropsychiatry context and the probability of bias and placebo effects are considerable, the subjects and the main investigator, the assessor, would be blinded. Therefore, the primary general evaluations, neuropsychological assessments, and patient preparation for neuroimaging will be executed by a trained clinical psychologist, based on a table that every subject has a distinct code. Staff responsible for preparing trial medications and the randomization process will not be further involved in the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tehran University of Medical Sciencesl Sciences

Street address

6th floor of the Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-07-22, 1399/05/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.269

Health conditions studied

1

Description of health condition studied

Obsessive Compulsive Disorder (OCD)

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Symptom (Obsession and Compulsions) Severity Based on Yale Brown Obsessive Compulsive Disorder Scale

Timepoint

Assessment of Severity and pattern of symptoms : at the beginning of study and before the beginning of intervention, 2 weeks after the beginning of intervention, 4 weeks after the beginning of intervention, 6 weeks after the beginning of intervention, 8 weeks after the beginning of intervention,10 weeks after the beginning of intervention, 12 weeks after the beginning of intervention.

Method of measurement

Validated Yale Brown Obsessive Compulsive Disorder Scale

Secondary outcomes

1

Description

Neuro-Cognitive Functions

Timepoint

At the beginning of the study and then after 6th week and 12th week

Method of measurement

The Cambridge Neuropsychological Test Automated Battery (CANTAB)

2

Description

Functional organization of Large-Scale Brain Networks

Timepoint

At the Beginning of Study and then after 6th week and 12th week

Method of measurement

Functional Magnetic Resonance Imaging

Intervention groups

1

Description

Intervention group: This group, which includes subjects with a diagnosis of obsessive-compulsive disorder, will receive memantine hydrochloride (C12H21N•HCl) 10 mg twice daily in two 8-week phases (total sixteen weeks). Memantine, a non-competitive glutamate receptor antagonist, is used to treat moderate to severe Alzheimer's disease. Memantine blocks the effects of sustained and elevated levels of glutamate, which can impair neuronal function. In addition, memantine provides the conditions for increased expression of the N-methyl-diaspartate receptor gene, which causes glutamate to act at higher concentrations and actually increase the threshold. Memantine has also shown a negligible affinity for gamma-aminobutyric acid, benzodiazepine, dopamine, adrenergic, histamine, glycine and voltage-dependent receptors for calcium, sodium, or potassium. Memantine is well absorbed from the gastrointestinal tract and is linear in its therapeutic dose range. It is essentially excreted by the kidneys and unchanged in urine and has a terminal half-life of about 60 to 80 hours.

Category

Treatment - Drugs

2

Description

Control group: This group, which includes subjects with a diagnosis of obsessive-compulsive disorder, will receive placebo of memantine twice daily for two 8-week stages (total sixteen weeks).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Jami Neuropsychiatry Clinic

Full name of responsible person

Mohammad Arbabi

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2

Recruitment center

Name of recruitment center
Imam Hossein Medical & Educational Center

Full name of responsible person
Dr. Jamal Shams

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Ali Sahraian

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Sixth Floor, Central Organization of Tehran University of Medical Science, Qods Street

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Web page address
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mahmoudreza Hadjighassem

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Neuroscience

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mahmoudreza Hadjighassem

Position
Associate Professor

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Ph.D.

Other areas of specialty/work
Neuroscience

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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Lida Shafaghi
Position
PhD Student
Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information of the main (primary outcome) and the secondary outcomes like neurocognitive functioning and neuronal networks reorganization outcome could be shared.
When the data will become available and for how long
6 months after publication of results
To whom data/document is available
Research data will be available for the researchers of universities and scientific institutes and also relevant investigators of the industries.
Under which criteria data/document could be used
The data will be available, when the samples are taken out, all the stages of the project are completed and finalized, and the results are published.
From where data/document is obtainable
1. Dr Mahmoudreza Hdjighassem First Address: Neuroscience Group, Reihaneh Department, Keshavarz BLVD, Imam Khomeini Hospital Complex. Tehran. Second Address: 87, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv. Tehran. Cell Phone Number: 09126779102 Faculty Phone Number: 02143052000 Fax Number: 02188991117 Email Address: mhadjighassem@tums.ac.ir 2. Lida Shafaghi Address: 87, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv. Tehran. Cell Phone Number: 09123832340 Fcaulty Number: 0214305200 Email Address: Lidashafaghi@gmail.com
What processes are involved for a request to access data/document
In order to receive the information, firstly the applicants send the formal application to the correspondent of the present proposal, Dr. Hadjighassem (Associate Professor of the Department of Neuroscience and Addiction studies, School of Advanced Technologies in Medicine) and then they will be informed of the details of the data reception (including timing-that will be tried to be within the shortest possible interval- and the way of the addressing the available data like email or in person.
Comments