Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Efficacy of Memantine augmentation in moderate to severe obsessive-compulsive symptoms

Protocol summary

Study aim
Efficacy of memantine add-on to standard treatment of obsessive-compulsive disorder

Design
Randomized double-blind phase 3 clinical trial on 30 patients allocated to treatment groups by permuted block randomization with quadruple blocks

Settings and conduct
double-blind clinical trial on patients with moderate to severe obsessive-compulsive disorder at Kargarnezhad Hospital Clinic in Kashan, Iran. The psychiatrist responsible for the project and the executors and patients and the personnel distributing the medicine will be blind to the contents of the sealed packages of the medicine and the placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-Age: 18-60 years 2-Patients with obsessive-compulsive disorder based on Yale Brown scale and clinical interview based on DSM5 criteria. 3-Yale Brown score is greater than or equal to 15 4. No comorbid psychiatric disorder based on DSM5 5 - Do not have systemic diseases 6. Do not consume alcohol and substances 7. Receive informed consent 8. Not receiving psychotropic treatment for 6 weeks before screening Exclusion criteria: 1- Pregnancy and lactation in women of childbearing age or not having a safe method of contraception 2. Psychiatric disorders based on DSM5 3-Simultaneous somatic treatment 4-Simultaneous treatment with any other medicine 5. Receiving psychotropic treatment from 6 weeks before screening 6-Receiving any method of psychotherapy 7. History of memantine use 8- Patient's desire to leave the study

Intervention groups
Two 15 member groups, in the first group, memantine and sertraline tablets are given for 8 weeks, and in the second group, placebo and sertraline are given.

Main outcome variables
YBOC score,YBOC obsession subscale,YBOC compulsion subscale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201227049851N1**
Registration date: **2021-03-07, 1399/12/17**
Registration timing: **prospective**

Last update: **2021-03-07, 1399/12/17**
Update count: **0**

Registration date
2021-03-07, 1399/12/17

Registrant information

Name
Atefeh Sattarinezhad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 2332 5453

Email address
sattarinezhad-a@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-15, 1399/12/25

Expected recruitment end date
2021-04-20, 1400/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Efficacy of Memantine augmentation in moderate to severe obsessive-compulsive symptoms

Public title
"Efficacy of Memantine Add on Treatment in Obsessive Compulsive Disorder"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients who suffer from obsessive-compulsive disorder according to DSM V and clinical interview. Patients who have Yale-Brown Scores of 15 and above. Patients who give written consent for participating in the study.

Exclusion criteria:
Patients who are diagnosed with a comorbid DSM V psychiatric diagnosis. Patients who suffer from any systemic disease such as diabetes, hypo and hyperthyroidism,hypertension,hepatic failure or renal failure. Patients who use alcohol or any other substance. Patients who have received a psychotropic medicine during the last 6 months. Women who are pregnant or breastfeeding or do not use any certain contraceptive method. Patients who use concomitant somatic treatments. Patients who are under treatment with Acetyl Cysteine, buprenorphine or any other medicine Patients who receive any kind of psychotherapies.

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of assigning treatment is permuted block randomization with quadruple blocks according to the random number table . Thus, by collecting each qualified quadruple block, one of the serials AABB, ABAB, BAAB, BABA, BBAA, ABBA is randomly assigned to the items within each block. The serials were made according to the permutation formula P (x, y, z) = P (x) × P (Y) × P (Z), which for a block of 4, the number of permutations of the possible combination is 4! /2 !× 2 != 6 was obtained and probable sequences were made to its number based on it .Consequently, according to the so called instructions, the patient will be stratified into one of the groups A or B. The drugs prepared under the label A or B are mixed in a carton and provided to the project implementers.

Blinding (investigator's opinion)
Double blinded

Blinding description
The placebo prepared by Kashan University of Medical Sciences and the memantine tablet produced by Darupakhsh Company are prepared in the similar gelatin capsule coating in terms of appearance, size and color and taste, in matched and sealed packages. Sertraline produced by Sobhan Daroo Company is also provided by the project executors given to the patients. Drug distribution is done by a staff member of the clinic of Kargarnezhad Hospital who has not participated in any of the steps of preparation, packaging and coding. The distribution of medicine is done in 0,1,2 weeks and then once every two weeks at the so-called clinic.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Kashan University of Medical Sciences,Qotb Ravandi Blvd.

City
Kashan

Province
Isfehan

Postal code
73474-87159

Approval date
2021-02-24, 1399/12/06

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1399.238

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 Score
Timepoint
Weeks 0,2,4,8
Method of measurement
Yale Brown Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group :15 male and female patients between the ages of 18 and 60 years who have moderate to severe obsessive-compulsive disorder based on DSM V-based clinical interview and Yale Brown test score will be treated with treated with Sobhan Daru Company's Sertraline tablets and Daroo Pakhsh Memantine tablets. Sertraline tablets will be started with a daily dose of 50 mg and the dose is increased 50 milligrams every week up to 200mgs and continued until the end of the eighth week. Memantine tablets in a placebo-like gelatin coating will be started at 5 mg daily and increased to 10 mg daily at the end of the first week and continued at the same dose until the end of week 8. Patients will be visited in weeks 0, 1, 2, 4, and 8 and the Yale Brown questionnaire and the side effects checklist will be completed.
Category
Treatment - Drugs

2

Description
Control group: 15 male and female patients between 18 and 60 years of age with moderate to severe obsessive-compulsive disorder according to a DSM V based clinical interview and a Yale Brown questionnaire will be treated with Sertraline tablets of Sobhan Daru Company and the placebo prepared by Kashan University of Medical Sciences in similar gelatin capsule coatings for 8 weeks. Sertraline tablets produced by Sobhan Daru Company will be initiated with a dose of 50 mgs. The dose will be increased by 50 mgs every week up to 200 mg until the end of week 8. At the same time, patients will receive a placebo(Darupakhsh 1 mg tablet) containing gelatin capsule once a day from week 0 to the end of week 8.They will be visited in weeks 0, 1, 2, 4, and 8 and the Yale Brown questionnaire and the side effects checklist will be completed at weeks 0,2,4,8.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kargarnezhad hospital clinic,Kashan
Full name of responsible person
Atefeh Sattarinezhad
Street address
Kargarnezhad Hospital,Qotb Ravandi Blvd
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8715973446
Phone
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Email
sattarinezhad-a@kaums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamid Reza Banafsheh
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Web page address
http://research.kaums.ac.ir/Default.aspx?PageID=58
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kashan University of Medical Sciences
Proportion provided by this source
10
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
Kashan University of Medical Sciences
Full name of responsible person
Atefeh Sattarinezhad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
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Zahra Sepehrmanesh
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Email
sepehrmanesh_z@kaums.ac.ir
Web page address
http://pajouhan.kaums.ac.ir/webdocument/load.action?webdocument_code=8000&masterCode=17000101

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zahra Sepehrmanesh
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Professor
Latest degree
Subspecialist
Other areas of specialty/work
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City
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Province
Isfehan
Postal code
8715973446
Phone
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Email
sepehrmanesh_z@kaums.ac.ir
Web page address
http://kargarnejad.kaums.ac.ir/Default.aspx?PageID=48

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
Demographic characteristics of subjects, raw scores of Yale Brown tests, checklist of side effects
When the data will become available and for how long
Access period starts one year after the results are published
To whom data/document is available
Researchers working for academic and scientific institutes
Under which criteria data/document could be used
For metanalyses and systematic reviews and head to head studies
From where data/document is obtainable
Research Center of the Vice Chancellor for Research of Kashan University of Medical Sciences
What processes are involved for a request to access

data/document

Sending a request letter to the Vice Chancellor for Research of Kashan University of Medical Sciences

approved by the supervisor attending of the project

Comments